i-STAT®1
System Manual

Abbott
Point of Care

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Art: 714336-00E

Patents

CA 1,281,072; CA 1,303,175; CA 1,330,888; CA 2,002,848; CA 2,087,720; CA 2,087,966; CA 2,175,228; CA 2,193,000; CA 2,194,795; CA 2,221,178; EP 0408575; EP 0412119; EP 0434742; EP 0442969; EP 0505169; EP 0540691; EP 0543916; JP 2113412; JP 2521826; JP 2833809; JP 2948321; JP 3093274; JP 3105919; JP 3105922; JP 3137612; JP 3269553; JP 3392871; US 4,864,229; US 4,933,048; US 4,954,087; US 5,008,616; US 5,096,669; US 5,112,455; US 5,121,050; US 5,124,661; US 5,200,051; US 5,447,440; US 5,466,575; US 5,514,253; US 5,554,339; US 5,605,664; US 5,609,824; US 5,614,416; US 5,628,961; US 5,789,253; US 5,821,399; US 5,837,446; US 6,030,827; US 6,379,883; US 6,438,498; US 6,750,053; US D332,833; US D337,164

Symbol Technologies Corporation is the owner of US Patent Nos. 4,758,717; 5,130,520; 5,262,628; 5,396,055; 5,532,469.

Trademarks

i-STAT is a registered trademark of Abbott Laboratories. MediSense is a registered trademark of Abbott Laboratories. Precision and PCx are trademarks of Abbott Laboratories. Windows is a registered trademark of Microsoft Corporation.

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i-STAT 1 SYSTEM MANUAL CONFIGURATION

Please ensure that the contents of your System Manual are complete and up to date. In the event that your System Manual does not contain the current configuration, it is recommended that you contact your i-STAT support provider.

As of April 2007, your i-STAT®1 System Manual should be configured with the contents as listed below and in the order shown.

ITEM	**Art #**
Cover Sheet	714336-00E
Configuration Sheet	714419-00Y
Table of Contents	714362-00H
Section 1	714363-00H
Section 2	714364-00F
Section 3	714365-00C
Section 4	714366-00B
Section 5	714367-00C
Section 6	714368-00E
Section 7	714369-00D
Section 8	714370-00C
Section 9	714371-00D
Section 10	714372-00G
Section 11	714373-00C
Section 12	714374-00C
Section 13	714375-00C
Section 14	714376-00F
Section 15	714377-00G
Section 16	714378-00C
Section 17	714379-00E
Section 18	714380-00D
Section 19	714381-00D
Section 20	714382-00D
Section 21	714383-00D
Section 22	714384-00D
CTI Sheets	
Introduction	714258-00L
Sodium	714173-00H
Potassium	714174-00F
Chloride	714175-00G
Urea Nitrogen/BUN	714176-00G
Glucose	714177-00G
Hematocrit/Hemoglobin	714178-00G
Ionized Calcium	714179-00H
PO_2 / sO_2	714180-00G
pH	714181-00J
PCO_2/HCO_3/BE/AG	714182-00N
Total Carbon Dioxide/TCO_2	716661-00C
Creatinine	714183-00J
Lactate	714184-00F
Celite ACT	714185-00E
Kaolin ACT	715878-00D
Prothrombin Time PT/INR	715236-00G
Cardiac Troponin I	715595-00G
Creatine Kinase MB / CK-MB	716675-00C
B-Type Natriuretic Peptide/BNP	716969-00C

Technical Bulletin

Analyzer Coded Messages 714260-00E
Proficiency Testing and the i-STAT System 714262-00N
Hematocrit Determination in the i-STAT System and Comparison to Other Methods. 714261-00C
Installation Guide for the Central Data Station to Receive Data from a Philips Clinical Data Server 714270-00C
K_2EDTA and K_3EDTA Customization for Hematocrit on the i-STAT System 716240-00B
Calibration Verification and the i-STAT System 715209-00D
ACT Test Result Options: Prewarmed vs. Non-Prewarmed Result Calibration Modes for the i-STAT 1 Analyzer 715617-00C
Support Services 716144-00E

MSDS Sheets **

i-STAT Controls and Calibration Verification Solutions 715023-00A
i-STAT CHEM8+ Controls and Calibration Verification Solutions 716660-00A
Trinity Biopool PT Normal and Abnormal Control 715024-00A
Biopool International Normal and Abnormal ACT Control 715025-00A
Hematronix Meter Trax Controls 715026-00A
UltraLife Lithium Battery (i-STAT Analyzers) 715027-00A
Harding Energy Systems, Inc.
NiMH Rechargeable Battery (i-STAT 1 Analyzer) 716663-00A
TEIG Nickel Hydride Rechargeable Battery (i-STAT1 Analyzer) 716056-00A
Nickel Metal Hydride Rechargeable Battery (Martel Printer) 715030-00B
i-STAT 65µL Capillary Tube Dispensers 715939-00A
Cardiac Marker Human Serum Control and Calibration Verification Solutions 716024-00C
RNA® Medical Hematocrit Calibration Verification Controls 716608-00A
RNA® Medical Hematocrit Controls 716607-00A
Clinqua Cardiac Marker Controls 716971-00A
More Diagnostics BNP Controls and Calibration Verification Set 717117-00B

Procedure Manual

Procedure Manual 714446-00D

Contents

INTRODUCTION .... 1 - 1

This Manual .... 1 - 1
Intended Use .... 1 - 1
Overview of the i-STAT System .... 1 - 1
Components .... 1 - 2
Selection of Components .... 1 - 2
Summary of the Procedure .... 1 - 2
Data Management .... 1 - 3
Interfacing .... 1 - 3
Note Regarding System Reliability .... 1 - 3
Symbols .... 1 - 3
Warranty .... 1 - 7

SYSTEM COMPONENTS

i-STAT 1 ANALYZER .... 2 - 1

Introduction .... 2 - 1
Before You Use the Analyzer .... 2 - 1
Specifications .... 2 - 2
Software .... 2 - 3
Power .... 2 - 3
Disposable Batteries .... 2 - 3
Rechargeable Battery .... 2 - 3
Low Battery Warning .... 2 - 3
Cartridge Port .... 2 - 4
Test Strip Port .... 2 - 4
Infrared Communication Window .... 2 - 5
Thermal Control .... 2 - 5
Barometric Pressure Sensor .... 2 - 5
Cartridge Test Cycle .... 2 - 5
Strip Test Cycle .... 2 - 5
Data Entry .... 2 - 6
Storage of Results .... 2 - 6
LCD Display and Backlight .... 2 - 7
Audible Indicator .... 2 - 7
Time Out .... 2 - 7
Keypad .... 2 - 8
i-STAT 1 Menu Tree .... 2 - 9
Test Menu .... 2 - 10
Administration Menu .... 2 - 10
Analyzer Status .... 2 - 11
Data Review .... 2 - 11
Quality Tests .... 2 - 12
Customization .... 2 - 13
Set Clock .... 2 - 17
Transmit Data .... 2 - 17
Utility .... 2 - 17
Laser Barcode Scanner .... 2 - 18
Prompts and Messages .... 2 - 19

i-STAT CARTRIDGE .... 3 - 1

Contents .... 3 - 1
Standardization and Calibration .... 3 - 3
Packaging .... 3 - 3
Storage Conditions .... 3 - 4
Disposal .... 3 - 4

PRECISION PCx AND PCx PLUS BLOOD GLUCOSE TEST STRIPS .... 4 - 1

ELECTRONIC SIMULATOR .... 5 - 1

Internal Simulator .... 5 - 1
External Simulator .... 5 - 1
Operating Characteristics .... 5 - 2
Cleaning the Simulator .... 5 - 2

i-STAT 1 DOWNLOADER .... 6 - 1

Function .... 6 - 1
Specifications .... 6 - 2
Power Supply .... 6 - 2
Downloader/Recharger Indicator LEDs .... 6 - 3
Power Requirements .... 6 - 3
Cautions .... 6 - 3
Transmitting Data from Downloader to the Data Manager .... 6 - 4
Transmitting Data from Downloader/Recharger to the Data Manager .... 6 - 4
Transmitted Information .... 6 - 4
Troubleshooting .... 6 - 5
Charging the Rechargeable Battery .... 6 - 5
Charging Rechareable Battery in the External Recharge Compartment .... 6 - 6

PORTABLE PRINTER .... 7 - 1

MARTEL Printer .... 7 - 1
Overview .... 7 - 1
Specifications .... 7 - 1
Supplies Provided with Printer .... 7 - 2
Power .... 7 - 2
Loading Paper .... 7 - 2
Printing Directly from the Analyzer .... 7 - 3
Printing Via a Downloader .... 7 - 3
Printing Many Results .... 7 - 4
What is Printed .... 7 - 4
Cautions .... 7 - 4
Troubleshooting .... 7 - 5

DATA MANAGEMENT .... 8 - 1

Introduction .... 8 - 1
Components .... 8 - 1
Data Manager .... 8 - 2
i-STAT Central Data Station Version 5 Software .... 8 - 2
Downloader and Downloader/Recharger .... 8 - 3
IR Link .... 8 - 3
LIS/HIS Interface .... 8 - 3
Standard Data Management Configuration .... 8 - 4
Connecting Components .... 8 - 4

CUSTOMIZATION .... 9 - 1

PROCEDURES

SAMPLE COLLECTION .... 10 - 1
Specimen Collection .... 10 - 1
Venipuncture - General .... 10 - 1
Venipuncture - pH, PCO2, Electrolyte, Chemistry, and Hematocrit Tests .... 10 - 2
Venipuncture - Coagulation Tests .... 10 - 4
Venipuncture - Glucose Test Strip .... 10 - 4
Arterial Puncture - General .... 10 - 4
Arterial Puncture - Blood Gas, Electrolyte, Chemistry, and Hematocrit Tests .... 10 - 4
Arterial Puncture - Coagulation Tests .... 10 - 6
Arterial Puncture - Glucose Test Strips .... 10 - 6
Indwelling Line .... 10 - 6
Skin Puncture .... 10 - 7
Sample Transfer Devices .... 10 - 7
References .... 10 - 8

PROCEDURE FOR HANDLING CARTRIDGES .... 11 - 1
Preparation for Testing .... 11 - 1
Filling and Sealing Cartridge Using Transfer Device .... 11 - 2
Filling and Sealing PT/INR Cartridges Using Direct Fingerstick Sampling .... 11 - 2
Filling and Closing a cTnI Cartridge Using Transfer Device .... 11 - 3
Inserting and Removing the Cartridge From the Analyzer .... 11 - 4
Incorrect Procedure .... 11 - 5

PROCEDURE FOR CARTRIDGE TESTING .... 12 - 1
Cautions .... 12 - 1
Performing Patient Analysis with Cartridge – Information First Disabled .... 12 - 2
Performing Patient Analysis with Cartridge – Information First Enabled .... 12 - 4
Interpretation of Displayed Results .... 12 - 7
Troubleshooting .... 12 - 9

PROCEDURES FOR GLUCOSE TEST STRIP TESTING .... 13 - 1
Operating Guidelines for All Samples .... 13 - 1
Performing Patient Glucose Assay with Test Strip .... 13 - 2
Caution .... 13 - 4
Interpretation of Displayed Results .... 13 - 5
Troubleshooting .... 13 - 6

QUALITY CONTROL .... 14 - 1
Overview .... 14 - 1
Quality Control for i-STAT Cartridges and the Analyzer's Cartridge Test Cycle .... 14 - 1
Controls for Blood Gas/Electrolyte/Metabolite Cartridges (Except CHEM8+ Cartridges) .... 14 - 3
Correction of PO2 at Extreme Altitude .... 14 - 5
Controls for CHEM8+ Cartridges .... 14 - 6
RNA® Medical Hematocrit Control .... 14 - 8
Meter Trax™ Controls for Hematocrit Sensor .... 14 - 9
Controls for ACT Cartridges .... 14 - 9
Controls for PT/INR Cartridges .... 14 - 10
Controls for cTnI Cartridges .... 14 - 12
Cliniqa Liquid QC™ Cardiac Marker Controls for i-STAT .... 14 - 13
i-STAT BNP Controls .... 14 - 14
Performing Electronic Simulator Test .... 14 - 15
Procedure for Internal Electronic Simulator .... 14 - 15
Procedure for External Electronic Simulator .... 14 - 15
Troubleshooting Failed Electronic Simulator Test .... 14 - 16
Checking the Thermal Probes in the i-STAT Analyzers .... 14 - 17

Procedure to Check Ambient Temperature .... 14 - 19
Performing Control Test on Cartridge .... 14 - 19
Troubleshooting Out-of-Range Control Results on Cartridge .... 14 - 21
Controls for Glucose Test Strip .... 14 - 21
Recommendations for Glucose Test Strips .... 14 - 22
Performing Control Test with Glucose Strip .... 14 - 22
Troubleshooting Out-of-Range Results on Test Strips .... 14 - 24
Quality Control Log Sheets .... 14 - 25

CALIBRATION VERIFICATION .... 15 - 1

Calibration Verification for
Blood Gas/Electrolyte/Metabolite Cartridges (Except CHEM8+ Cartridges) .... 15 - 1
i-STAT Calibration Verification Set .... 15 - 2
i-STAT CHEM8+ Calibration Verification Set .... 15 - 3
i-STAT Cardiac Marker Calibration Verification Set .... 15 - 5
i-STAT BNP Calibration Verification Set .... 15 - 6
RNA® Medical Hematocrit Calibration Verification Controls .... 15 - 7
Verification Procedure for Hematocrit .... 15 - 8
Verification Procedure for ACT .... 15 - 9
Procedure for Cartridges .... 15 - 10
Troubleshooting Cartridge Tests .... 15 - 11
Linearity/Calibration Verification Test for Test Strips .... 15 - 12
Troubleshooting Strip Tests .... 15 - 13

PROFICIENCY or EXTERNAL QUALITY CONTROL TESTING .... 16 - 1

Purpose .... 16 - 1
General Procedure .... 16 - 1
Procedure For Cartridges .... 16 - 1
Troubleshooting .... 16 - 3
Procedure for Test Strips .... 16 - 4

CARE AND SOFTWARE UPDATES

ROUTINE CARE of the ANALYZER and DOWNLOADER .... 17 - 1

Drying a Wet Analyzer or Downloader .... 17 - 1
Cleaning the Analyzer and Downloader .... 17 - 1
Removing and Replacing Disposable Batteries .... 17 - 2
Removing and Replacing the Rechargeable Battery .... 17 - 3

UPDATING THE SOFTWARE .... 18 - 1

CLEW .... 18 - 1
Application Software .... 18 - 1
Software Updates .... 18 - 1
Updating Analyzer Software: JAMMLITE Utility .... 18 - 2
Troubleshooting .... 18 - 8
Analyzer-to-Analyzer Software Updates .... 18 - 9
Performing a JAMS and CLEW update on an i-STAT 1 Analyzer using
the Customization Workspace .... 18 - 10

TROUBLESHOOTING THE ANALYZER

TROUBLESHOOTING THE ANALYZER .... 19 - 1

Introduction .... 19 - 1
Information Needed .... 19 - 1
Startup Messages .... 19 - 2

Test Cycle Messages and Quality Check Codes ..... 19 - 3
Glucose Strip Errors ..... 19 - 6
No Display ..... 19 - 7
"Cartridge Locked" Not Removed ..... 19 - 7

THEORY

THEORY ..... 20 - 1
Analyzer Functions ..... 20 - 1
Electrochemical Measurements ..... 20 - 3
Determination of Test Results ..... 20 - 4
Determination of Cell Concentration ..... 20 - 5
CPB ..... 20 - 5
Determination of Coagulation Endpoints ..... 20 - 7
Quality Control and the i-STAT System ..... 20 - 7
Quality Control and the i-STAT Coagulation Tests ..... 20 - 13

DOWNLOADER PROGRAMMING

DOWNLOADER PROGRAMMING AND WIRING ..... 21 - 1
Programming the Network Downloaders ..... 21 - 1
Wiring the Downloaders ..... 21 - 6

CENTRAL DATA STATION

CENTRAL DATA STATION ..... 22 - 1
i-STAT License Agreement and Warranty for Central Data Station Program ..... 22 - 1
Installation Of The Central Data Station ..... 22 - 3
General Procedures and Conventions ..... 22 - 5
Customization of the Central Data Station ..... 22 - 9
Interface Program Customization ..... 22 - 15
Overview of the Central Data Station Program ..... 22 - 17
Administration Tools ..... 22 - 19
Instrument and Location Workspace ..... 22 - 19
Operator Workspace ..... 22 - 25
Operator List Import ..... 22 - 31
Database Maintenance ..... 22 - 33
Inventory Workspace ..... 22 - 37
Customization Workspace ..... 22 - 43
User Administration Workspace ..... 22 - 51
Password Management ..... 22 - 53
Data Viewers ..... 22 - 55
Data Export ..... 22 - 62
Monitors ..... 22 - 63
Reports ..... 22 - 65
System ..... 22 - 68
Windows Operating System and Language Support ..... 22 - 69

CARTRIDGE AND TEST INFORMATION

Cartridge and Test Information

Sodium

Potassium

Chloride

BUN/Urea

Glucose

Hematocrit/Hemoglobin

Ionized Calcium

PO_2

pH

PCO_2

Total Carbon Dioxide/TCO_2

Creatinine

Lactate

Celite ACT

Kaolin ACT

Prothrombin Time PT/INR

Cardiac Troponin I

Creatine Kinase MB/CK-MB

B-Type Natriuretic Peptide/BNP

TECHNICAL BULLETINS

MSDS SHEETS

PROCEDURE MANUAL

INTRODUCTION 1

This Manual

This manual describes the i-STAT®1 Analyzer and the Central Data Station software. Related sections are grouped behind tabs.

The i-STAT Portable Clinical Analyzer and the Philips Medical Systems Blood Analysis Module (formerly supplied by Agilent Technologies, and Hewlett-Packard, Inc., for the Viridia CMS Patient Monitors) are described in a separate manual.

Intended Use

The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for *in vitro* quantification of various analytes in whole blood and with the Abbott MediSense® Precision PCx™ Blood Glucose Test Strip for the *in vitro* quantification of glucose in whole blood. Analyzers, cartridges, and test strips should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

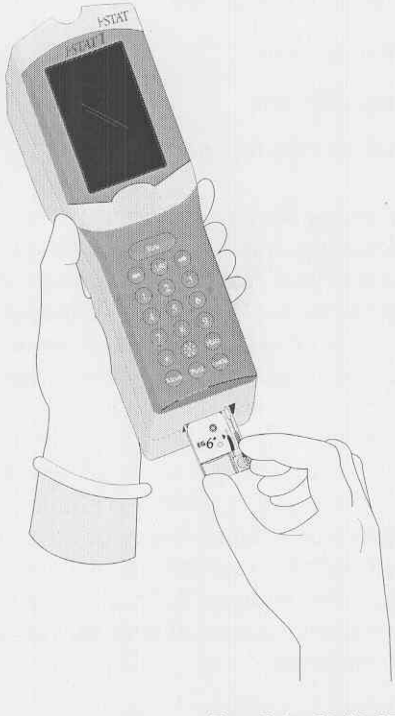
In the USA, for the purpose of CLIA compliance, the i-STAT system is categorized as Non-Waived complexity.

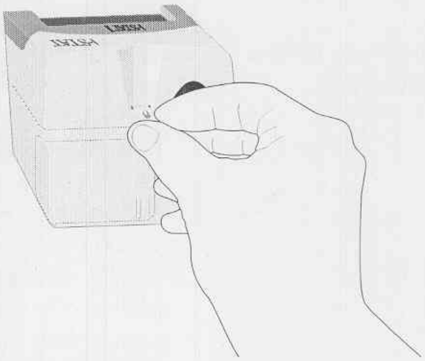
Overview of the i-STAT System

The i-STAT System incorporates a comprehensive group of components needed to perform blood analysis at the point of care. A portable handheld analyzer, a cartridge with the required tests, and 2-3 drops of blood will allow the caregiver to view quantitative test results for blood gas, chemistry and coagulation tests in approximately two minutes. Glucose results are available from the Precision PCx Blood Glucose Test Strip in as little as 20 seconds on the handheld analyzer.

Portable printers and infrared communication devices allow all patient information obtained at the bedside to be printed on demand and transmitted to centralized information systems for record keeping and billing.

The Central Data Station program provides system management tools including real-time monitoring of testing and operator competency.





Components

The i-STAT System consists of:

- i-STAT Cartridges
- Abbott MediSense Precision PCx and PCx Plus Blood Glucose Test Strips
- i-STAT 1 Analyzer
- i-STAT Portable Clinical Analyzer
- Philips Medical Systems Blood Analysis Module (used in conjunction with a patient monitor)
- Portable Printer
- Quality Assurance Materials
  - Electronic Simulator
  - Control Solutions
  - Calibration Verification Set (for cartridges)
  - Linearity Assessment Kit (for test strips)
- Data Management System
  - i-STAT 1 Downloader
  - i-STAT 1 Downloader/Recharger
  - IR Link for Portable Clinical Analyzer
  - Data Manager
    - Central Data Station (data management software for cartridges)
    - QC Manager (data management software for test strips)
- Data Manager Printer
- LIS/HIS Interface Software

Selection of Components

The selection of system components is dependent on factors unique to each facility such as:

- Types of tests to be performed
- Number of testing sites
- Number of tests per site
- System administration requirements

Summary of the Procedure

To perform cartridge testing, the operator fills a cartridge with sample, seals the cartridge with its snap closure, and inserts the cartridge into the analyzer. Inserting the cartridge activates the analyzer. Alternatively, the cartridge test cycle can be initiated from the keypad/menu system. The unit-use cartridge contains all components to perform one or more tests including: calibrating solution, sample handling system, sensors and reagents. The analyzer automatically controls all steps in the testing cycle, which may include: fluid movement, reagent mixing, calibration and thermal control. Quality checks are performed continuously throughout the test cycle. Operator and patient IDs and patient chart information can be entered. When the test cycle is completed, results are displayed and the test record is stored. To perform glucose test strip testing, the operator selects a the glucose strip option from the menu, scans the test strip barcode, inserts the test strip into the analyzer test strip port and applies sample to the test strip. This degree of automation, along with the ability to test fresh whole blood, eliminates many sources of error as well as time-consuming and costly steps inherent in other methods.

Data Management

Test records can be transmitted to the Data Manager where they can be printed and/or transmitted to the Laboratory Information System or Hospital Information System. An optional portable printer enables the operator to print results at the point of care.

Interfacing

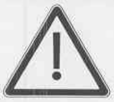
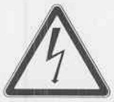
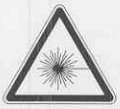
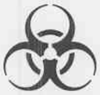
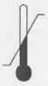
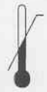
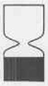
The Data Manager can be interfaced to a Laboratory Information System (LIS) or Hospital Information System (HIS) to automate billing and patient record keeping.

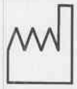
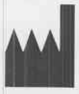
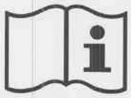
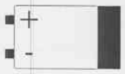
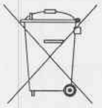
Note Regarding System Reliability

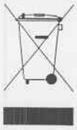
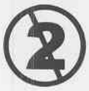
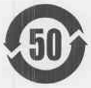
The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, Abbott Point of Care Inc. recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

Symbols

Symbols can be helpful in reducing the necessity for translating important information into multiple languages, particularly where space is limited. The following symbols may be found on components of the i-STAT System.

Symbol	Definition
	Attention: See instructions for use.
	Caution: Risk of electrical shock.
	Laser radiation hazard symbol.
	Biological Risks.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Upper limit of temperature. The upper limit for storage is adjacent to the upper arm
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used. An expiration date expressed as YYYY-MM means the product cannot be used past the last day of the month specified.

Symbol	Definition
LOT	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
REF	Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.
SN	Serial number. The serial number will appear adjacent to this symbol.
MN	Model number. The model number will appear adjacent to this symbol.
	Date of manufacture.
	Manufacturer
IVD	In vitro diagnostic medical device.
EC REP	Authorized Representative for Regulatory Affairs in the European Community.
▽Σ	Contains sufficient for < n > tests.
⎓	Direct Current (DC)
∿	Alternating Current (AC)
⧈	Class II Construction
	Consult instructions for use or see System Manual for instructions.
CONTROL	Control
C ETL® US LISTED	Signifies that the product bearing the ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010A-1 CAN/CSA C22.2 No. 1010.1-92
i immuno	i/immuno: Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.
	Battery: i-STAT 1 Analyzer low battery icon (flashes on lower left side of display screen).
	Separate waste collection for this electrical/electronic item indicated.

Symbol	Definition
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
BODxxxx-xx	Born On Date: the label BODxxxx-xx defines the year and month of manufacture.
	Do not reuse.
	This symbol is used for compliance with the China RoHS regulation(s). It indicates in years the Environmentally Friendly Use Period (EFUP) for the labeled electronic medical device product

Symbol	The following symbols are used on the i-STAT 1 keypad.
SCAN	Key used to scan information into the analyzer.
ABC	Key used to enter letters.
ENT ↵	Key used to enter information.
MENU	Key used to access the analyzer's menu.
PRT	Key used to print a test record.
⏻	Key used to turn the analyzer off and on.

Symbol	The following symbols are used on the i-STAT Portable Clinical Analyzer Keypad
DIS	Key used to activate the display.
ENT	Key used to enter information.
PRT	Key used to print a test record.
CLR	Key used to clear an incorrect entry.

Symbol	The following symbols are used on i-STAT Value Assignment Sheets
$\bar{X}$	Mean
R	Range

Symbol	TEST
Na	Sodium
K	Potassium
Cl	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
pH	pH
PCO_2	Partial pressure of carbon dioxide.
PO_2	Partial pressure of oxygen.
iCa	Ionized Calcium
BUN/UREA	Urea nitrogen/Urea
Hct	Hematocrit
ACTc **Celite ACT**	Activated Clotting Time with Celite® activator.
ACTk **Kaolin ACT**	Activated Clotting Time with Kaolin activator.
PT/INR	Prothrombin Time / International Normalized Ratio
Hb	Hemoglobin
TCO2	Total carbon dioxide concentration.
HCO3	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extra cellular fluid)
AnGap	Anion Gap
sO2	Oxygen saturation
cTnI	Cardiac Troponin I
CK-MB	Creatine Kinase MB Isoenzyme
BNP	B-type Natriuretic Peptide

Warranty

Abbott Point of Care Inc. warrants this medical product (excluding disposable or consumable supplies) against defects in materials and workmanship for one year from the date of shipment. If Abbott Point of Care Inc. receives notice of such defects during the warranty period, Abbott Point of Care Inc. shall, at its option, either repair or replace products which prove to be defective. With respect to software or firmware, if Abbott Point of Care Inc. receives notice of defects in these products during the warranty period, Abbott Point of Care Inc. shall repair or replace software media and firmware which does not execute their programming instructions due to such defects. Abbott Point of Care Inc. does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free. If Abbott Point of Care Inc. is unable, within a reasonable time, to repair or replace any product to a condition as warranted, Buyer shall be entitled to a refund of the purchase price upon return of the product to Abbott Point of Care Inc..

Note: Warranty rights may vary from state to state, province to province and country to country.

Limitations of Warranty

The foregoing warranty shall not apply to defects resulting from:

1 Improper or inadequate maintenance by Buyer or an unauthorized person,

2 Using accessories and/or consumables that are not approved by Abbott Point of Care Inc.,

3 Buyer-supplied software or interfacing,

4 Unauthorized repairs, modifications, misuse, or damage caused by disposable batteries, or rechargeable batteries not supplied by Abbott Point of Care Inc..

5 Operating outside of the environmental specifications of the product, or

6 Improper site preparation or maintenance.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE AND NO OTHER WARRANTY, WHETHER WRITTEN OR ORAL, IS EXPRESSED OR IMPLIED. ABBOTT SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Selling or Leasing the i-STAT System

If you sell an i-STAT analyzer, please notify Abbott Point of Care Inc. so that we can enter the new owner into our software update database. If you rent an i-STAT analyzer and do not intend to provide software updates to the leaser, please notify Abbott Point of Care Inc. so that we can enter the leaser into our software database.

i-STAT 1 ANALYZER 2

INTRODUCTION

The i-STAT 1 Analyzer is used in conjunction with i-STAT cartridges for the simultaneous quantitative determination of specific analytes in whole blood and with the MediSense Precision PCx and PCx Plus Glucose Test Strips for the quantitative measurement of glucose in whole blood.

Refer to the Cartridge and Test Information section of this manual for information on analytes that can be measured using i-STAT cartridges.

BEFORE YOU USE THE ANALYZER

Install Batteries

Two disposable lithium batteries are supplied with the analyzer. See the Care of the Analyzer section in this manual for the procedure to install the disposable batteries. If a rechargeable battery is to be used, the disposable batteries can be used while the rechargeable battery pack is charged in the Downloader/Recharger. Charge rechargeable batteries fully before use. See the i-STAT 1 Downloader section for this procedure. When using a rechargeable battery, store the disposable battery carrier for possible future use.

Check Date and Time

Press the On/Off key and check that the date and time at the top of the display are correct. To change the date and time, see Administration Menu in this section.

Check Software

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have standard CLEW and application software. If a different CLEW and/or application software is in use in your facility, it must be installed in new, repaired or replaced analyzers before they are put into use. Check the Analyzer Status page for the installed CLEW and application software. See under "Standardization and Calibration" in section 3 of this manual for an explanation of CLEW.

Customization

Analyzers can be customized for many site-specific testing requirements. See the Customization section for a list of customizable parameters and their default values. To change the customization profile via the analyzer keypad see "Customization" under "Administration" in this section of the manual. To change the customization profile via the Central Data Station, see the "Customization Workspace" in the Central Data section of this manual.

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have the factory default settings in the customization profile, as indicated by the DEFAULT0 on the Analyzer Status page. If analyzers in your facility do not use the default customization profile, the appropriate customization profile should be installed before a new, repaired or replaced analyzer is put into use.

The i-STAT 1 Analyzer is shipped with the glucose test strip functionality disabled. The glucose test strip functionality can be enabled through the Customization function on the Central Data Station or analyzer.

Older i-STAT 1 analyzers may have the test strip port blocked. The test strip port can be unlocked as follows. A small flat-head screwdriver is needed to remove the plug.

1 Hold the analyzer with the test strip port facing you and the display facing up.

2 Hold the screwdriver with the blade horizontal. Carefully insert the blade into the horizontal gap under the plug.

3 Pry up gently until the plug pops free. Take care not to force the screwdriver into the port.

4 Remove the screwdriver and then remove the plug. The plug can be replaced if necessary.

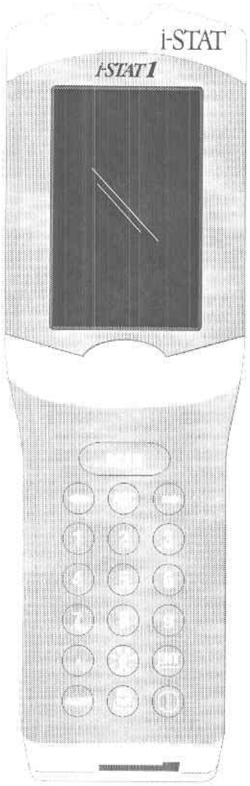
Perform Quality Check

Use the Electronic Simulator to verify the cartridge-reading performance of new or repaired analyzers.

Use QC protocols to verify the test strip-reading performance of new or repaired analyzers.

DESCRIPTION

Specifications



DIMENSIONS	Width 7.68 cm (3.035 in.) Length 23.48 cm (9.245 in.) Depth 7.24 cm (2.85 in.)
WEIGHT	With rechargeable battery 650 grams (22.9 oz.) With disposable battery 635 grams (22.4 oz.)
POWER	Two 9-volt lithium batteries, or rechargeable battery.
CALIBRATION	Factory: electronic, mechanical, thermal, pressure
MEMORY/CLOCK BACKUP POWER	Lithium Battery
DISPLAY	Dot matrix supertwist liquid crystal
COMMUNICATION LINK	Infrared light-emitting diode (LED)
OPERATING TEMPERATURE	15-40°C (59-104°F) for Medisense strip testing 16-30°C (61-86°F) for i-STAT cartridge testing
TRANSPORT TEMPERATURE	-10-46°C (14-115°F)
RELATIVE HUMIDITY	90% (maximum) non-condensing
BAROMETRIC PRESSURE	300-1000 mmHg
LASER SCANNER	Complies with U.S. 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser Notice No. 50, dated July 26, 2001. EN 60825-1:1994 + A1:2002 + A2:2001 IEC 60825-1:1993 + A1:1997 + A2:2001

Software

All analyzer functions are controlled by application software that can be updated as additional tests and features are developed. Coefficients used to maintain the accuracy of cartridge results over time are programmed into the analyzer via CLEW software updates every four months. See under "Standardization and Calibration" in section 3 of this manual for an explanation of CLEW.

Note: Calibration information for the glucose test strips is included in the barcode on the foil packet in which each test strip is packaged. The analyzer requires that this information be scanned or entered via the keypad before the test strip can be inserted into the analyzer.

Power

There are two power options for the analyzer: disposable and rechargeable. The analyzer is shipped with two disposable 9-volt lithium batteries and a battery carrier. Lithium batteries may be ordered from i-STAT or obtained locally. ULTRALIFE® lithium batteries (ULTRALIFE Batteries, Inc., Newark, NY, USA) are recommended. Only i-STAT rechargeable batteries may be used.

Battery Compartment

The battery compartment is located at the display end of the analyzer next to the laser barcode scanner window. The procedure for changing disposable and rechargeable batteries can be found in the Routine Care of the Analyzer and Downloader section of this manual.

Disposable Batteries

The analyzer requires two 9-volt lithium batteries. The lifetime for a set of batteries is mainly dependent on the mix of cartridges in use. Cartridges that require thermal control consume more energy because of heating. Coagulation and immunoassay cartridges consume more energy because of the longer test cycle. A minimum of 400 thermally controlled cartridge uses, about 100 coagulation cartridges, 50 immunoassay cartridges, or about 1,000 glucose test strips can be expected before replacement is necessary. Backlighting, if used continuously, may reduce battery life up to 50%. Extensive laser scanning will affect battery life slightly.

The lithium batteries should be removed from the analyzer when long periods, such as six months, of no use are anticipated.

Rechargeable Battery

The analyzer can be powered by a nickel-metal-hydride rechargeable battery. The battery capacity for one full charge is 30% (minimum) of the capacity of one set of disposable lithium batteries (see above). If the analyzer is not in use, batteries will lose approximately 10-30% of their charge over 30 days if not recharged.

Store rechargeable batteries in a cool dry place when not in use.

The battery recharges when the analyzer is placed in a Downloader/Recharger. The battery pack can be removed from the analyzer and placed in the separate recharging compartment on the Downloader/Recharger. Full recharge from a discharged state takes approximately 40 hours. The analyzer will display "Low Battery" when battery recharge is needed.

Caution: Do not short circuit, incinerate or mutilate the recharegable batteries.

Low Battery Warning

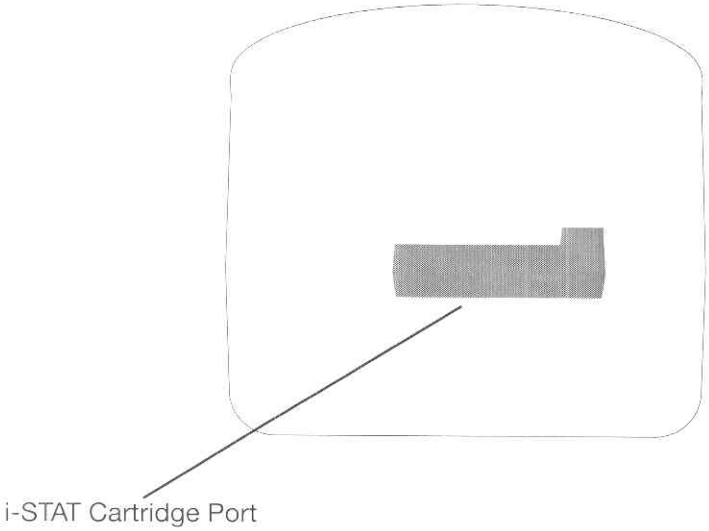
The analyzer will display "Low Battery" when the On/Off key is pressed and a flashing battery icon on the result screens when battery replacement is needed. Data is not lost when batteries are fully discharged.

Additional Power

A lithium battery inside the analyzer maintains the clock/calendar and customization profile. This battery should last seven years.

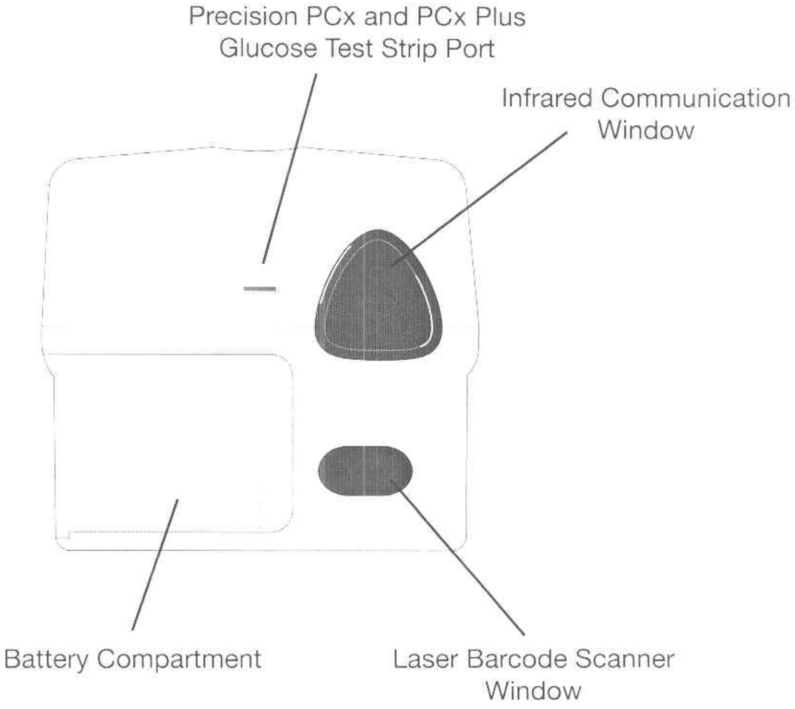
Cartridge Port

Cartridges and the Electronic Simulator are inserted into the analyzer through the cartridge port on the keypad end of the analyzer. Unless the analyzer is customized to require information input before a test, inserting a cartridge or Electronic Simulator initiates the test cycle (i.e., the analyzer does not need to be turned on first). The cartridge and test strip ports cannot be used simultaneously.


i-STAT Cartridge Port

Test Strip Port

Precision PCx and PCx Plus Blood Glucose Test Strips are inserted into the analyzer through the test strip port on the display end of the analyzer when prompted by the analyzer.


Precision PCx and PCx Plus
Glucose Test Strip Port
Infrared Communication Window
Battery Compartment
Laser Barcode Scanner Window

Infrared Communication Window

The Infrared Communication Window provides the analyzer with two-way communication to the Central Data Station via a Downloader, allows analyzer-to-analyzer software updates, and allows analyzer-to-printer communication for printing.

Thermal Control

The analyzer contains a thermal control subsystem of thermistors and heating contact wires that controls the temperature of the sensors and fluids that come into contact with the sensors to 37°C. This subsystem is activated automatically when a cartridge containing tests which require thermal control at 37°C is inserted into the analyzer.

Barometric Pressure Sensor

The analyzer contains a solid-state barometric pressure sensor, which determines the ambient atmospheric pressure used for the $\boldsymbol{P}O_2$ sensor calibration.

Cartridge Test Cycle

An operator starts a cartridge test cycle either by inserting a cartridge into the analyzer or by selecting the i-STAT Cartridge option from the Test or Quality Tests Menu.

The analyzer:

- makes electrical contact with the cartridge
- identifies the cartridge type
- releases calibration fluid to the sensors (when applicable)
- mixes sample and reagent (when applicable)
- measures barometric pressure
- heats the sensors to 37°C (when required by the test)
- measures electrical signals generated by the sensors and calibration fluid (when applicable)
- displaces the calibrant solution with sample (when applicable)
- measures electrical signals generated by the sensors and sample
- accepts the operator and patient IDs scanned or entered by the operator
- accepts chart page information
- calculates and displays results
- stores results

Strip Test Cycle

An operator starts a test strip test cycle by selecting the PCx Glucose Strip option from the Test or Quality Tests Menu.

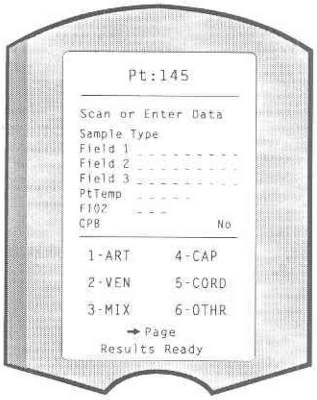
The analyzer:

- accepts test strip lot data
- prompts the operator to insert the test strip
- prompts the operator to apply the sample
- measures electrical signals generated by the glucose sensor and sample
- accepts the operator and patient IDs scanned or entered by the operator
- accepts chart page information entered by the operator
- calculates and displays results
- stores results

Data Entry

Data that can be scanned into the analyzer or entered via the keypad include:

- Operator ID
- Patient ID, Proficiency ID, or Simulator ID
- Cartridge and Strip Lot Number
- Control Lot Number
- Cal Ver Kit Lot Number
- Comment codes for patient and control results
- Chart Page
    - Sample Type
    - Patient Temperature - The analyzer will interpret numbers between 50.0 and 110.0 as degrees Fahrenheit and between 10.0 and 45.0 as degrees centigrade. When a patient temperature is entered, blood gas results will be displayed at both 37°C and the patient's temperature.
    - FIO2
    - Free Fields: three fields, up to 9 characters each



```
        Pt:145
Scan or Enter Data
Sample Type
Field 1 _________
Field 2 _________
Field 3 _________
PtTemp  _____
FIO2    ___
CPB                No
 1-ART      4-CAP
 2-VEN      5-CORD
 3-MIX      6-OTHR
       → Page
   Results Ready
```

See the Customization section in this manual for barcode formats recognized by the analyzer.

Storage of Results

The analyzer automatically stores up to 5,000 test records. A test record consists of:

- a set of results
- the date and time the test was performed
- the cartridge type
- all information entered by barcode scanner or keypad including:
    - Operator and Patient IDs
    - Lot numbers for controls, cartridges and test strips
    - Chart page data
    - Serial number of the Electronic Simulator
- the serial number of the analyzer
- the number of times the analyzer has been used
- the software and CLEW versions installed in the analyzer
- the name of the analyzer's customization profile

Quality Check Codes, which may appear during the test cycle indicating a problem with the sample, calibration, sensors, mechanical or electrical functions of the analyzer, are also stored.

The Analyzer Status option under the Administration Menu lists the number of stored records as "Total" and "Unsent" records. Test records are stored as "Unsent" until the analyzer uploads data to the Central Data Station at which time the records are marked as sent. The analyzer can be customized to display a Memory Full prompt or to disable testing until data is transmitted to the Central Data Station. Otherwise, the oldest data is overwritten when the memory becomes full. Stored test records can be reviewed through the Data Review option on the Administration Menu screen described later in this section.

LCD Display and Backlight

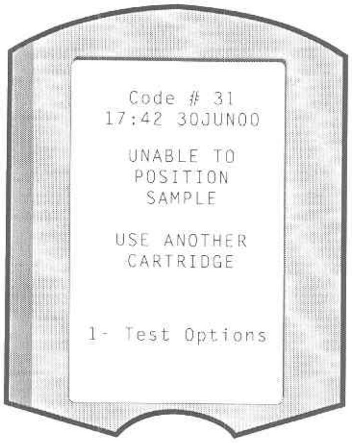
Test results, operator prompts and other messages are displayed on the analyzer's LCD Screen. The backlight for the display is turned on and off by pressing the 0 key for one second. The backlight will automatically turn off after ninety seconds and when the analyzer powers down or is turned off. The backlight cannot be turned on while data entry screens are displayed.

Audible Indicator

The analyzer will beep to indicate:

- whenever a key is pressed.
- a successful barcode entry.
- sample detection on glucose test strip tests.
- results are ready.
- a Quality Check Message is displayed.

The analyzer can be customized to disable beeping when a key is pressed or results or messages are displayed.



```
Code # 31
17:42 30JUN00

UNABLE TO
POSITION
SAMPLE

USE ANOTHER
CARTRIDGE


1- Test Options
```

Time Out

The analyzer automatically turns off after a certain period of inactivity.

- **Results displayed:** Results are displayed for 2 minutes before the analyzer turns off provided that a mandatory Comment Code prompt is not displayed. This Inactivity Time Out default time can be increased using Customization.

  If a mandatory Comment Code prompt is displayed, the analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater. In the case of a missed required Comment Code, results will be stored and "_ _ _" will be entered as the Comment Code.

- **Prompting for mandatory data when results are ready for display:** The analyzer will turn off after 15 minutes or after the Inactivity Time Out, whichever is greater, if there is no response to a mandatory data prompt. A mandatory data prompt is a prompt for information that must be entered before pending results are displayed.

  In the case of a missed mandatory data prompt, results will not be stored and the test record will state "Test Cancelled by Operator."

- **Waiting for insertion of cartridge:** After the prompt "Insert Cartridge" is displayed, the analyzer will wait 15 minutes for the operator to insert a cartridge unless the analyzer is in the Proficiency path, in which case the analyzer will wait 5 minutes. If a cartridge is not inserted, the analyzer will turn off. This timeout cannot be customized.

- **Waiting for insertion of test strip:** After the prompt "Insert Strip" is displayed, the analyzer will wait 2 minutes for the operator to insert a test strip. If a test strip is not inserted, the analyzer will turn off. This timeout cannot be customized.

- **Other:** The analyzer will turn off after 2 minutes of inactivity (no keys pressed) in all other circumstances.

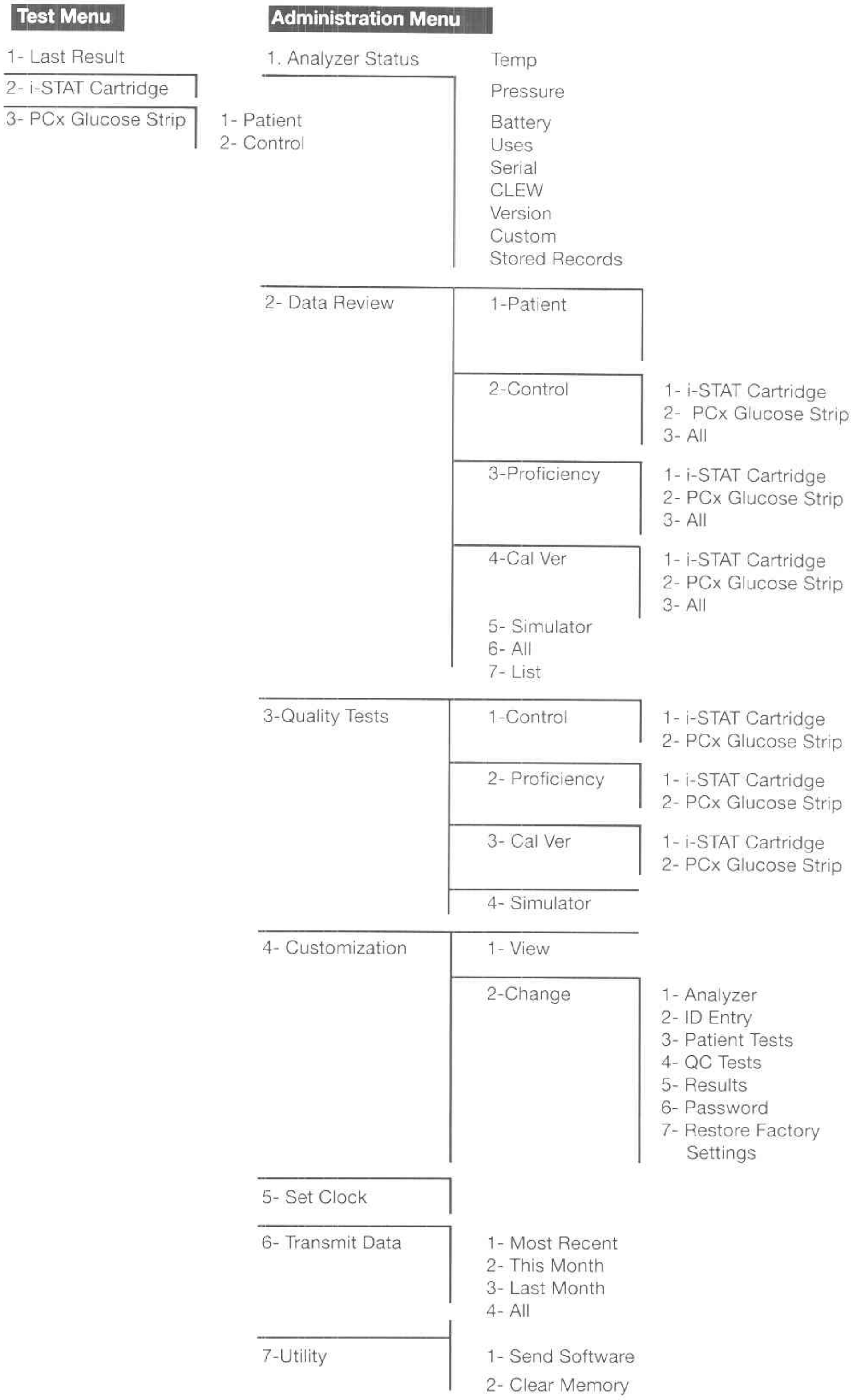
Keypad

There are 19 keys located directly below the display. When using the keypad to enter information, the number of dashes in the data entry line will indicate how many characters can be entered on the line. The dash where the next entry will be placed will flash.

Key	Function
SCAN	Activates the barcode scanner. Information that can be entered into the analyzer via the scanner includes: operator ID, patient ID, control, cartridge and test strip lot number, patient chart data and comment codes.
⬅ ➡	Used to move the cursor on the Set Clock screen and to move up and down the alphabet when the ABC key is pressed. The ➡ (right arrow) key is used as a page key to move from one screen to the next. When Patient ID Recall is enabled, the ➡ key will recall the last patient ID when the analyzer is prompting for Patient ID. The ⬅ (left arrow) key is used to backspace and clear keypad entries, and to move backward through the screens within a menu.
ABC	Used to enter alpha characters on data entry screens. When the ABC key is pressed the letter A is entered. The arrow keys are used to move up and down the alphabet. To enter a second letter, press the ABC key once to move to the next position and again to enter an A. To enter a number after a letter, press a numbered key. To erase a letter, press the ABC key to move to the next position, then use the ⬅ key to backspace and clear the letter.
0 – 9	Used to enter digits on data entry screens and to select menu options and stored records.
•	Enters a decimal point or a comma separator according to the analyzer's Customization Profile.
☼	Used to turn the screen backlight on and off.
Enter ENT	Used to respond to a prompt to complete an action, such as entering an operator or patient ID via the keypad.
MENU	Used to return to the previous menu and switch between the Test and Administration Menus.
Print PRT	Used to print either directly to the portable printer or to the portable printer attached to a Downloader.
On/Off ⏻	Turns the analyzer on or off. When the analyzer is on, the On/Off key must be pressed for a second to turn the analyzer off. This key is inactive when a test is in progress and when the analyzer is prompting for mandatory data.

i-STAT 1 Menu Tree

There are two main menus: The Test Menu and the Administration Menu. If the glucose test strip function is disabled, test strip options will not be displayed.



Test Menu

- 1- Last Result
- 2- i-STAT Cartridge
- 3- PCx Glucose Strip
  - 1- Patient
  - 2- Control

Administration Menu

- 1. Analyzer Status
  - Temp
  - Pressure
  - Battery
  - Uses
  - Serial
  - CLEW
  - Version
  - Custom
  - Stored Records
- 2- Data Review
  - 1-Patient
  - 2-Control
    - 1- i-STAT Cartridge
    - 2- PCx Glucose Strip
    - 3- All
  - 3-Proficiency
    - 1- i-STAT Cartridge
    - 2- PCx Glucose Strip
    - 3- All
  - 4-Cal Ver
    - 1- i-STAT Cartridge
    - 2- PCx Glucose Strip
    - 3- All
  - 5- Simulator
  - 6- All
  - 7- List
- 3-Quality Tests
  - 1-Control
    - 1- i-STAT Cartridge
    - 2- PCx Glucose Strip
  - 2- Proficiency
    - 1- i-STAT Cartridge
    - 2- PCx Glucose Strip
  - 3- Cal Ver
    - 1- i-STAT Cartridge
    - 2- PCx Glucose Strip
  - 4- Simulator
- 4- Customization
  - 1- View
  - 2-Change
    - 1- Analyzer
    - 2- ID Entry
    - 3- Patient Tests
    - 4- QC Tests
    - 5- Results
    - 6- Password
    - 7- Restore Factory Settings
- 5- Set Clock
- 6- Transmit Data
  - 1- Most Recent
  - 2- This Month
  - 3- Last Month
  - 4- All
- 7-Utility
  - 1- Send Software
  - 2- Clear Memory

TEST MENU

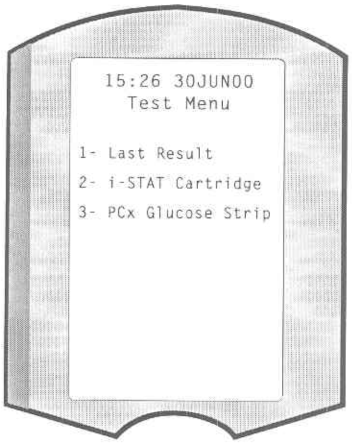
The Test Menu is displayed when the analyzer is turned on using the On/Off key.

The options are:

- 1 - Last Result
- 2 - i-STAT Cartridge
- 3 - PCx Glucose Strip
  - 1 - Patient
  - 2 - Control

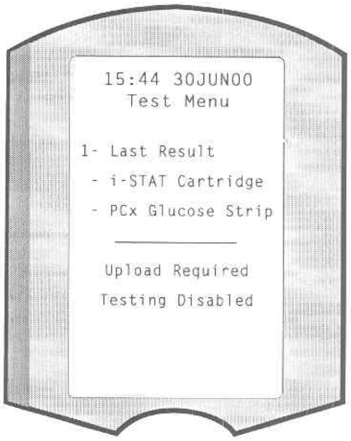
Options 2 and 3 are used for testing patient samples. For the glucose test strip, controls can also be tested from the Test Menu. Testing controls from the Test Menu rather than option 3 – Quality Tests under the Administration Menu may be more convenient for end users who test glucose test strip control samples on a daily basis.

Note: If the analyzer is customized with test strip testing disabled, test strip options will not be displayed. If the analyzer is customized to disable testing under certain conditions, the disabled option will be listed without its number so that it cannot be selected.



```
15:26 30JUN00
  Test Menu

1- Last Result
2- i-STAT Cartridge
3- PCx Glucose Strip
```



```
15:44 30JUN00
  Test Menu

1- Last Result
 - i-STAT Cartridge
 - PCx Glucose Strip

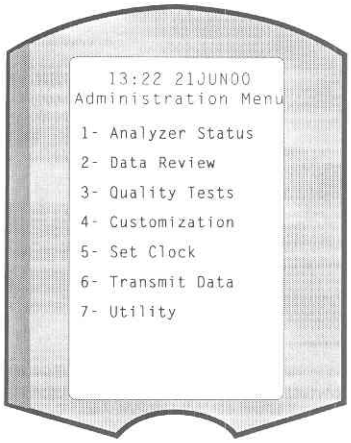
 Upload Required
 Testing Disabled
```

ADMINISTRATION MENU

Overview

The Administration Menu is accessed by pressing the Menu key from the Test Menu screen. The options are:

- 1 - Analyzer Status
- 2 - Data Review
- 3 - Quality Tests
- 4 - Customization
- 5 - Set Clock
- 6 - Transmit Data
- 7 - Utility

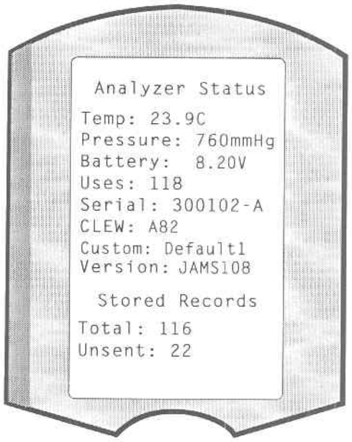


```
    13:22 21JUN00
Administration Menu
1- Analyzer Status
2- Data Review
3- Quality Tests
4- Customization
5- Set Clock
6- Transmit Data
7- Utility
```

Analyzer Status

The Analyzer Status screen contains information about the condition or "status" of the analyzer. Fresh readings are made whenever this option is selected.

Temp	Room temperature.
Pressure	Barometric pressure.
Battery	Battery voltage.
Uses	Total number of cartridge, simulator and test strip test cycles, whether or not results reported.
Serial	Serial number of the analyzer.
CLEW	Version of standardization data installed in the analyzer.
Version	Version of application software installed in the analyzer.
Custom	Customization profile name.
Stored Records	Total: The number of test records in the analyzer's memory. The maximum storage capacity is 5,000 test records, which include records with results and Quality Check Codes for patients and controls both liquid and electronic. Unsent: The number of test records that have not been transmitted to the Central Data Station.

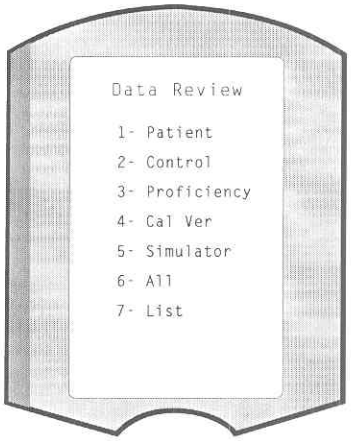


```
Analyzer Status
Temp: 23.9C
Pressure: 760mmHg
Battery:  8.20V
Uses: 118
Serial: 300102-A
CLEW: A82
Custom: Default1
Version: JAMS108
Stored Records
Total: 116
Unsent: 22
```

Data Review

The Data Review function allows the operator to review stored results by the categories listed below. The number of test records stored is indicated at the bottom center of the screen as x/y where x is the record on the screen and y is the total number of stored records in the selected category. The 1 and 2 keys are used to scroll through the stored records as indicated on the bottom right and left of the screen. The most recent test record is always in the first position. The right arrow key is used to page through the screens of the displayed record.

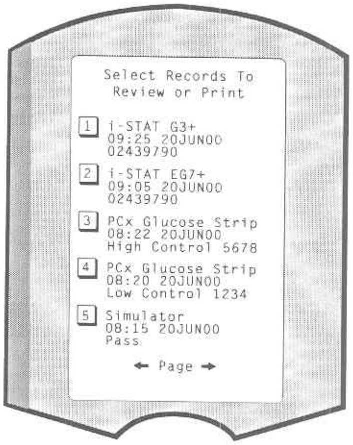
1 - Patient	The records for a patient are recalled by scanning or entering via the keypad the Patient ID. If no Patient ID is entered, all patient tests are recalled.
2 - Control	1 – i-STAT Cartridge 2 – PCx Glucose Strip 3 - All
3 - Proficiency	1 – i-STAT Cartridge 2 – PCx Glucose Strip 3 - All
4 - Cal Ver	1 – i-STAT Cartridge 2 – PCx Glucose Strip 3 – All
5 - Simulator	All external and internal Electronic Simulator records.
6 - All	All test records in the analyzer's memory.



```
Data Review
1- Patient
2- Control
3- Proficiency
4- Cal Ver
5- Simulator
6- All
7- List
```

7 - List

Records are listed with Cartridge type or PCx Glucose Strip, date and time of test, and patient ID, control lot, proficiency ID, or Cal Ver lot and test level as applicable. Any number of test records can be selected for viewing or printing using the number keys. Pressing the number key corresponding to a record selects a record; pressing the number key a second time deselects the record.


Select Records To
Review or Print

1 i-STAT G3+
09:25 20JUN00
02439790

2 i-STAT EG7+
09:05 20JUN00
02439790

3 PCx Glucose Strip
08:22 20JUN00
High Control 5678

4 PCx Glucose Strip
08:20 20JUN00
Low Control 1234

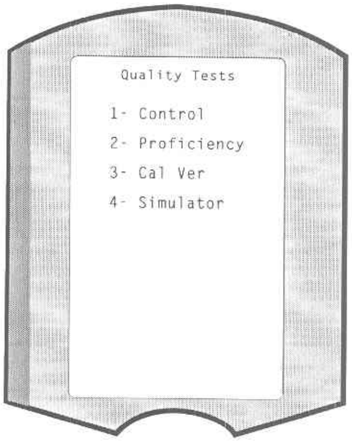
5 Simulator
08:15 20JUN00
Pass

To view one or more records, select the records and press the Enter key. To print records, select the records and press the Print key.

Quality Tests

Non patient tests can be initiated from the Quality Tests menu. Options are:

1 - Control	
2 - Proficiency	(external quality control)
3 - Cal Ver	(Calibration Verification for cartridges and Linearity Test for test strips)
4 - Simulator	(cartridge-reading function only)



When options 1 - 3 are selected, the operator further selects:

1 – i-STAT Cartridge

2 – PCx Glucose Strip

When testing is initiated from one of these options, the analyzer prompts the operator to scan or enter the Operator ID; the Control Lot Number, Proficiency ID, Cal Ver Kit Lot Number, or Simulator ID as applicable; and the Cartridge Lot Number or Test Strip Lot Number as applicable.

When the Quality Tests option is used, results can be reviewed according to the corresponding options under the Data Review option.

Note: The Test Menu option for test strips includes both a Patient and Control option. Results for test strip controls run from the Test and Quality Tests menus are stored together.

Customization

Analyzers can be customized for site-specific testing characteristics and requirements. A complete list of customizable parameters and their default values can be found in the Customization section. An analyzer can be customized via the keypad or via the Central Data Station. Items that cannot be customized via the analyzer's keypad are operator lists, test strip lists, reference and action ranges, sample types and order of items on the Chart page.

The Central Data Station's Customization function can be used to create one customization profile for all analyzers or different profiles for different locations. When the Customization function is enabled, the profiles are transmitted to the analyzers when they are placed in a Downloader.

Caution: If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB: Automatically Adjust" or "CPB: Do Not Adjust" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional affect of pump fluid during cardiopulmonary bypass surgery. If an analyzer customized for the CVOR as "CPB: Automatically Adjust" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If an analyzer customized as "CPB: Do Not Adjust" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

It is recommended that only one method, the Central Data Station or the keypad, be used to customize all analyzers within a site. If both methods are in use, and the Customization function is not disabled on the Central Data Station, any changes made to the profile of an analyzer via the keypad will be overwritten the next time the analyzer is placed in a Downloader.

The customization profile of an analyzer is identified in the Customization option under the Administration Menu on the analyzer. DEFAULT0 indicates that the analyzer has factory settings. When an analyzer has been customized via the Central Data Station (CDS), the name assigned to the profile by the CDS is listed. If the default or CDS profile is changed on the analyzer, the profile is listed as 00000000.

Note: The i-STAT Portable Clinical Analyzer and the Philips Medical Systems Blood Analysis Module can be customized only from the Central Data Station. However, not all customizable features apply to these two analyzers. See the i-STAT System Manual for the i-STAT Portable Clinical Analyzer for customizable features for this analyzer and the Blood Analysis Module.

Viewing the Customization Profile

Select **4- Customization** from the Administration Menu, select **1- View** then select from the Customization Menu:

1 - Analyzer

2 - ID Entry

3 - Patient Tests

4 - QC Tests

5 - Results

Select a category to review. Use the ← and → keys to scroll through the preferences for each category and use the ← key to return to the Customization menu.

The Customization review option on the analyzer does not display the certified operator list or the valid test strip lot list. These items can be viewed on the Central Data Station.

Changing the Profile

To customize via the analyzer keypad, select **4- Customization** from the Administration Menu, then select **2- Change**. If the analyzer has already been customized with a password, enter the password. If not, press the Enter key. (It is recommended that the Change function be password protected). Then make selections from the Customization menu. To change a setting, select the item by pressing the number key correponding to the item, then select the setting. Use the → key to view all items. After all items have been set, turn the analyzer off to save and activate the settings.

Note:

○ Outside the USA, the following changes should be considered: language, unit set, date format and decimal separator.

1 - Analyzer

first page
  1 Language
  2 Date Format
  3 Sound
  4 Auto-transmit
  5 Memory Full

second page
  1 Batch Mode
  2 Inactivity Timeout
  3 Upload Schedule
  4 PCx Glucose Test Strip
  5 Clock Password

third page
  1 Sync Clock

- 2 - ID Entry
  - 1 – Operator

    first page

    1 Minimum Length
    2 Maximum Length
    3 Repeat ID
    4 Manual Entry
    5 Code I2of5

    second page

    1 Code 128
    2 EAN-8, EAN-13
    3 Codabar
    4 Code 93
    5 Code 39, Full ASCII

    third page

    1 Code 39, Check Digit
    2 Truncate First x Digits
    3 Truncate Last x Digits
    4 Print ID

  - 2 – Patient

    first page

    1 Minimum Length
    2 Maximum Length
    3 Repeat ID
    4 ID Recall
    5 Manual Entry

    second page

    1 Code I2of5
    2 Code 128
    3 EAN-8, EAN-13
    4 Codabar
    5 Code 93

    third page

    1 Code 39, Full ASCII
    2 Code 39, Check Digit
    3 Truncate First x Digits
    4 Truncate Last x Digits

- 3 - Patient Tests

  first page

  1 Cartridge Auto-chart
  2 Strip Auto-chart
  3 Cartridge Information
  4 Cartridge Barcode
  5 Cartridge Lot Number

  second page

  1 Comment Code, In Range
  2 Comment Code, Out of Range
  3 Strip Sample Type
  4 Result Output
  5 Downloader Lockout

4 - QC Tests

- 1 – Simulator
  - 1 External Simulator
  - 2 External Simulator Schedule Option
  - 3 Internal Simulator
  - 4 Internal Simulator Schedule Option
- 2 – Strip Controls
  - 1 Schedule
  - 2 Mid Level Control
  - 3 Comment Code, In Range
  - 4 Comment Code, Out of Range

5 - Results

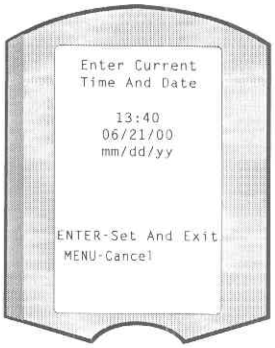
- 1 – Units and Ranges
- 2 – Options
  - first page
  - 1 Decimal Separator
  - 2 Test Selection
  - 3 Hematocrit (CPB and EDTA)
  - 4 Base Excess
  - 5 ACT-C Cal Options
  - second page
  - 1 ACT-K Cal Options
  - 2 Print Reference Ranges

6 - Password

7 - Restore Factory Settings

Set Clock

If the analyzer is customized with a password, the Set Clock function will be password protected. If a password has not been assigned, pressing the Enter key will display the time and date screen. Use the arrow keys to move the cursor to the digit to be changed. Use a number key to change the digit. Press Enter to accept the changes or Menu to cancel the changes. An invalid entry, such as 13 for a month, will not be accepted.

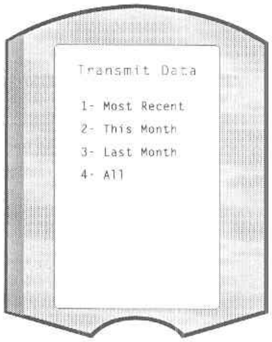


The format of the date on this screen can be customized using the Central Data Station Customization function, as mm/dd/yy or dd/mm/yy. The analyzer recognizes years in which February has 29 days.

The analyzer can be customized using the Central Data Station to synchronize or update the real time clock to the Central Data Station's clock at the time of each download. This option eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Saving Time. Otherwise, the clock must be manually changed for Daylight Savings Time changes.

Transmit Data

Unsent test records are automatically transmitted to the Central Data Station when an analyzer is placed in a Downloader or Downloader/Recharger. In some cases it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:



1 – Most Recent

2 – This Month

3 – Last Month

4 – All

Most Recent is the result from the last cartridge or test strip tested.

The analyzer can be customized using the Central Data Station to apply a date range limit to the Transmit All functions.

Auto-transmit is temporarily disabled when the Transmit Data option is selected to allow the user to control transmission of data.

Utility

The Utility menu can be password protected using the Customization function on the analyzer or Central Data Station.

1 – Send Software: Allows the analyzer to transmit software to another analyzer. See the Software Update section of this manual.

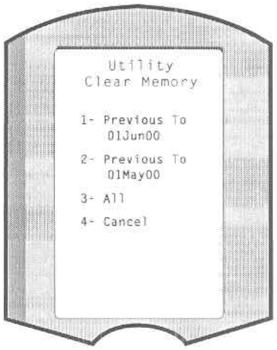
2 – Clear Memory: Erases results from the analyzer's memory. Options are:

  1 – Previous to 01MMMYY (where MMMYY is current month and year, such as 01JUN00)

  2 – Previous to 01mmmyy (where mmmyy is previous month and year, such as 01May00)

  3 – All

  4 – Cancel



LASER BARCODE SCANNER

Laser Barcode Scanner

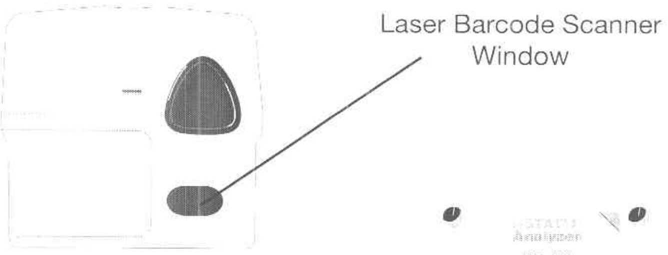
The barcode scanner is used to scan barcode information into the analyzer. Parameters that can be entered into the analyzer via the scanner include: operator and patient IDs, control, cartridge and test strip lot numbers, comment codes and patient chart data. The laser beam emerges from the recessed window on the front of the analyzer adjacent to the battery compartment. The laser beam automatically turns off after 3-4 seconds or after the barcode is successfully scanned.

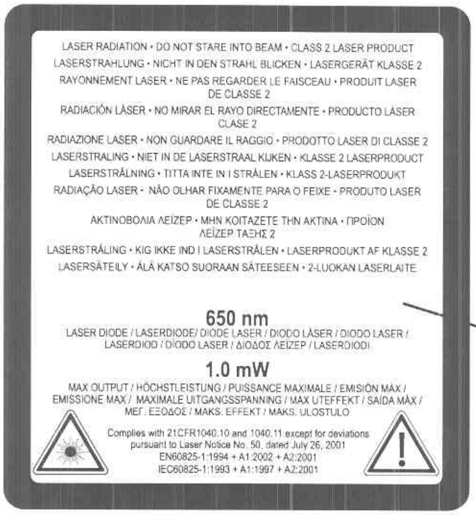
Laser Specifications

The barcode scan engine is manufactured by Symbol Technologies Corporation. The scan engine contains a laser diode that emits laser radiation at a frequency of 650 nm. The scan engine outputs power (i.e., the power output of the engine if removed from this product) up to 1.9 mW in scanning mode. The scanner in this product only operates when the Scan key is pressed. Symbol Technologies Corporation intends this engine to be used in a Class 2 device.

Warning Labels

Warning labels are shown below. The warning labels are located on the back or under-side of the analyzer, as shown. The location of the laser window from where the analyzer emits the laser beam is also shown below.



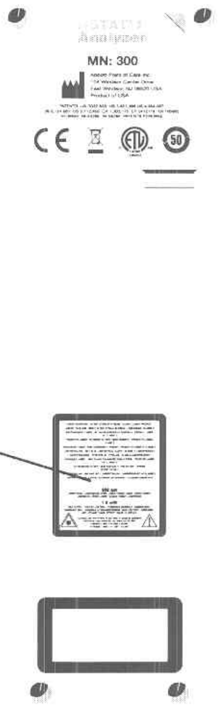


LASER RADIATION • DO NOT STARE INTO BEAM • CLASS 2 LASER PRODUCT
LASERSTRAHLUNG • NICHT IN DEN STRAHL BLICKEN • LASERGERÄT KLASSE 2
RAYONNEMENT LASER • NE PAS REGARDER LE FAISCEAU • PRODUIT LASER DE CLASSE 2
RADIACIÓN LÁSER • NO MIRAR EL RAYO DIRECTAMENTE • PRODUCTO LÁSER CLASE 2
RADIAZIONE LASER • NON GUARDARE IL RAGGIO • PRODOTTO LASER DI CLASSE 2
LASERSTRALING • NIET IN DE LASERSTRAAL KIJKEN • KLASSE 2 LASERPRODUCT
LASERSTRÅLNING • TITTA INTE IN I STRÅLEN • KLASS 2-LASERPRODUKT
RADIAÇÃO LASER • NÃO OLHAR FIXAMENTE PARA O FEIXE • PRODUTO LASER DE CLASSE 2
ΑΚΤΙΝΟΒΟΛΙΑ ΛΕΪΖΕΡ • ΜΗΝ ΚΟΙΤΑΖΕΤΕ ΤΗΝ ΑΚΤΙΝΑ • ΠΡΟΪΟΝ ΛΕΪΖΕΡ ΤΑΞΗΣ 2
LASERSTRÅLING • KIG IKKE IND I LASERSTRÅLEN • LASERPRODUKT AF KLASSE 2
LASERSÄTEILY • ÄLÄ KATSO SUORAAN SÄTEESEEN • 2-LUOKAN LASERLAITE

650 nm
LASER DIODE / LASERDIODE/ DIODE LASER / DIODO LÁSER / DIODO LASER / LASERDIOD / DÍODO LASER / ΔΙΟΔΟΣ ΛΕΪΖΕΡ / LASERDIODI

1.0 mW
MAX OUTPUT / HÖCHSTLEISTUNG / PUISSANCE MAXIMALE / EMISIÓN MÁX / EMISSIONE MAX / MAXIMALE UITGANGSSPANNING / MAX UTEFFEKT / SAÍDA MÁX / ΜΕΓ. ΕΞΟΔΟΣ / MAKS. EFFEKT / MAKS. ULOSTULO

Complies with 21CFR1040.10 and 1040.11 except for deviations
pursuant to Laser Notice No. 50, dated July 26, 2001
EN60825-1:1994 + A1:2002 + A2:2001
IEC60825-1:1993 + A1:1997 + A2:2001



Caution

Do not open the analyzer. The analyzer may only be opened by factory authorized service personnel. **Class 2 laser radiation when open; DO NOT stare into the laser aperture or the laser beam, or point the laser beam at other persons.**

Use of controls, adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.

Class 2 laser scanners use a low power, visible light diode. As with any bright light source, such as the sun, the user should avoid staring directly into the laser beam. Momentary exposure to a Class 2 laser is not known to be harmful.

Procedure

Before scanning, check to see what information is required by the displayed prompt. Hold the analyzer 3-12 inches (2.5 – 30.5cm) from the barcode to be scanned. An angle of about 10 degrees from perpendicular is best. Hold the analyzer and place the object to be scanned on a flat surface or, place the analyzer on a flat surface and hold the object in front of the analyzer. Avoid accidentally scanning other nearby items. Avoid pointing the beam into anyone's eyes.

STEP	ACTION
1	Press and hold down the Scan key to start the barcode scanner. The analyzer emits a visible red beam.
2	Position the analyzer and barcode so the beam forms a red line that spans the entire barcode. Increasing distance between the barcode and analyzer lengthens the red line. The analyzer does not need to touch the barcode.
3	When the analyzer accepts the barcode, it will beep in acknowledgement and automatically turn off the beam. The beam will also turn off after 3-4 seconds.
4	View the data that was scanned by the analyzer and verify that it is correct.
5	Release the Scan key.
Note:	If the Scan key is released as soon as the beep is heard, the next prompt will be displayed and the information scanned will not be able to be viewed.

PROMPTS AND MESSAGES

Prompts

Either before or during the testing cycle, the analyzer will display prompts that require an operator action or keypad entry, such as "Enter Operator ID." Prompts are described in the manual when used. Some prompts require input before results are displayed. Prompts for the following information are mandatory:

- Operator ID
- Patient ID
- Lot Number for Test Strips
- Lot Numbers for Quality Tests

Startup Messages

When the On/Off key is pressed the analyzer may display one or more startup messages. A startup warning message indicates an action that should be taken in the near future to maintain the analyzer in working condition. If the analyzer is customized to disable testing under certain conditions, a startup lockout message indicates the action that must be taken before testing is re-enabled.

Quality Check Messages

If the analyzer detects a problem during power on, a Quality Check message will be displayed indicating the action that must be taken before testing can begin.

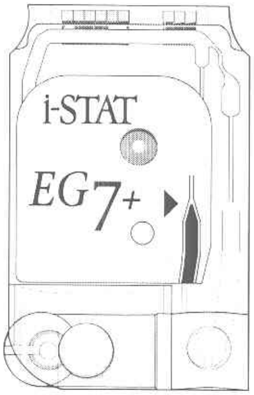
A Quality Check message will also be displayed and testing halted if the analyzer detects a problem during the test cycle.

Startup messages and Quality Check messages are described in the Troubleshooting section of this manual. "Upload Required, Testing Disabled" is an example of a startup lockout message, "Battery Low " is an example of a startup warning message, and "Unable to Position Sample" is an example of a quality check failure during the testing cycle.

Note: The "Cartridge Locked" or "Simulator Locked" prompt is always displayed when a cartridge or Electronic Simulator is inserted into the analyzer. Any attempt to remove a cartridge or Electronic Simulator before this prompt is removed from the screen may cause damage to the analyzer.

i-STAT CARTRIDGE 3

Contents

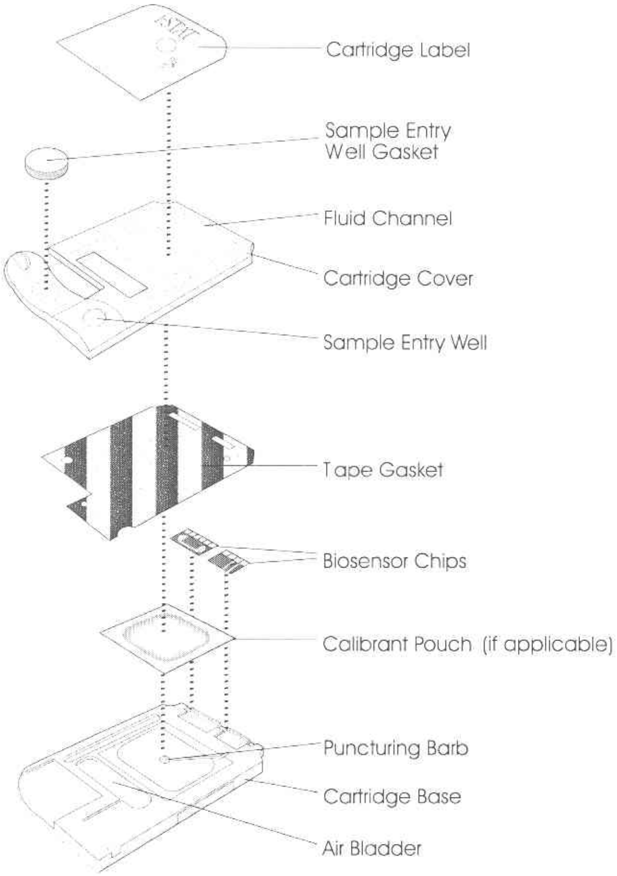


The unit-use disposable cartridge contains many of the subassemblies typically found in complex laboratory systems. Microfabricated thin film electrodes or sensors are assembled in unit-use cartridges containing:

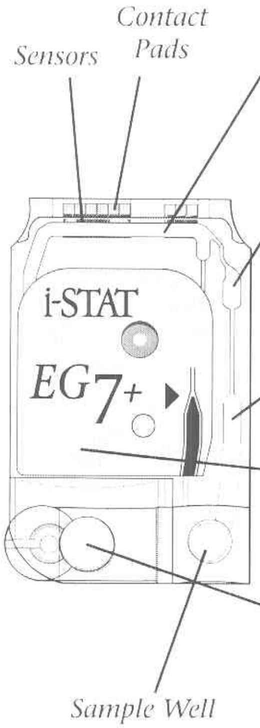
- calibrant solution in cartridges with sensors for blood gases, electrolytes, chemistries and hematocrit
- reagents in cartridges with sensors for coagulation
- sample handling system
- waste chamber
- an array of miniaturized sensors
- conductive pads to make electrical contact with the analyzer
- heating elements in cartridges requiring thermal control at 37 °C

See the Cartridge and Test Information Sheets for test-specific details.

The following diagram shows how a typical blood gas/chemistry cartridge is constructed.


Cartridge Label
Sample Entry Well Gasket
Fluid Channel
Cartridge Cover
Sample Entry Well
Tape Gasket
Biosensor Chips
Calibrant Pouch (if applicable)
Puncturing Barb
Cartridge Base
Air Bladder

Sample Handling System



Part	Function
Sensor Channel	The sensor channel directs the sample from the sample chamber to the sensors. An extension of this channel becomes a waste chamber to receive the calibrant solution as it is displaced by the sample.
Air Chamber	An air chamber is located in blood gas/electrolyte/chemistry/hematocrit cartridges between the sample chamber and sensor channel. This creates an air segment between the calibrant solution and the sample to prevent the two from mixing. The size of the air segment is monitored by the analyzer.
Sample Chamber	The sample chamber includes the sample well and the channel leading from the well up to the fill mark. When filled, the sample chamber contains sufficient sample for testing. Sample volume and placement are monitored by the analyzer.
Bladder	The bladder (concealed by the label) is connected to the sample well. The analyzer presses on the bladder to displace calibrant solution from the sensors, to move the sample from the sample chamber to the sensors or to mix sample and reagents.
Snap Closure	The snap closure creates an airtight seal necessary for proper fluid movement within the cartridge. The closure also ensures that calibrant and sample remain contained within the cartridge during the testing cycle and subsequent disposal. Immunoassay cartridges, such as cTnI, use a plastic slide enclosure clip.
Air Vent	An air vent on the underside of the cartridge, beyond the fluid front, allows the calibrant and the sample to flow forward, but not out of the cartridge.
Waste Chamber	A waste chamber (beneath the cartridge label) holds calibrant fluid after it has been used.

Sensors

The sensors are electrodes microfabricated on silicon chips. Electrodes have chemically sensitive coatings such as ion-selective membranes and enzyme layers. In cartridges that perform coagulation tests, reagents, such as clot activators, are coated on the plastic above the sensors. Each sensor is connected to a contact pad by a signal line. The sensors respond to the calibrant solution and the sample by producing measurable signals related to analyte concentration. The performance characteristics for each sensor are described in the Cartridge and Test Information section. The section on theory describes the measurement principles.

Contact Pads

The contact pads conduct the signals generated by the sensors to the analyzer. In order to function properly, care must be exercised not to contaminate the contact pads during cartridge handling.

Heating Elements

Cartridges that require thermal control at 37°C include heating elements on the underside of the sensor chips which are contacted and heated by the analyzer's thermal probes.

Standardization and Calibration

Standardization is the process by which a manufacturer establishes "true" values for representative samples. The sensors in the i-STAT cartridges are standardized against plasma methods used by major laboratory systems or, for blood gases, against tonometry. A multi-point calibration curve, the slope or sensitivity of which is defined by coefficients in the CLEW software, is derived for each sensor by this standardization process. These calibration curves are stable over many lots and only need to be adjusted if a change in a manufacturing process affects the curve or if the relationship between results on the i-STAT System and other major laboratory systems drifts. For the convenience of users, CLEW updates are scheduled three times a year.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the analyzer automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample's concentration from adjusted calibration curve.

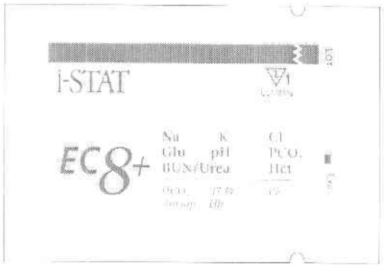
Packaging

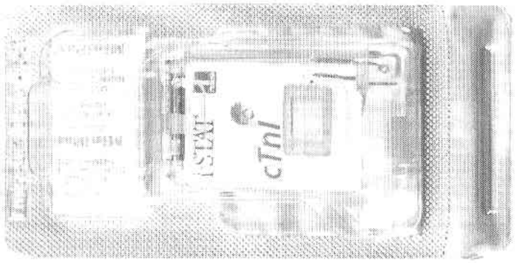
Each cartridge is sealed in a foil pouch or clear plastic portion pack for protection during storage.

Labeling on the carton, box and pouch/portion pack identify:

- the panel name.
- the tests included in the panel.
- the lot number.
- the expiration date of the cartridge.

If the pouch/portion pack has been punctured, the cartridge should not be used.





Storage Conditions

The main supply of cartridges should be stored at 2-8°C (35-46°F). Cartridges must be at room temperature before removing them from their pouches. Allow 5 minutes for an individual cartridge and one hour for a box of 25 cartridges to come to room temperature. Cartridges in use may be stored at room temperature (18-30°C or 64-86°F) for two weeks. The cartridge box contains a line used to indicate the two-week room temperature expiration date.

Disposal

Although the sample is contained in the cartridge, cartridges should be disposed of as biohazardous waste, according to local, state, and national regulatory guidelines.

PRECISION PCx and PCx™ Plus BLOOD GLUCOSE TEST STRIPS 4

Detailed Information

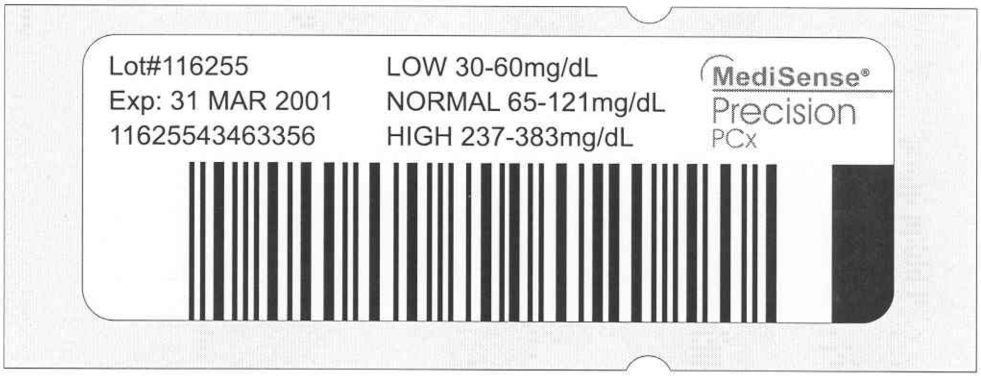
See the package insert included with each box of glucose test strips for information not included in this manual:

- Summary and Principle
- Reagents
- Storage and Handling
- Precautions
- Expected Results for Precision™, Precision•G®, MediSense® Control Solutions
- Limitations of the Procedure
- Performance Characteristics

Packaging

Each test strip is wrapped in a foil packet with a barcode label. This label holds the calibration information about the test strip, including:

- Lot number
- Expiration date
- Expected control solution ranges
- Lot-specific calibration information



Lot#116255
Exp: 31 MAR 2001
11625543463356

LOW 30-60mg/dL
NORMAL 65-121mg/dL
HIGH 237-383mg/dL

MediSense®
Precision
PCx

Example of test strip barcode label

Disposing of Waste

Discard used test strips in an approved biohazard container.

ELECTRONIC SIMULATOR 5

Overview

The Electronic Simulator, external and internal, is a quality control device for the analyzer's cartridge signal-reading function. It simulates two levels of electrical signals that stress the analyzer's cartridge signal detection function both below and above measurement ranges.

While the analyzer performs internal electronic checks and calibration during each test cycle, the Electronic Simulator test provides an independent check on the ability of the analyzer to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. An analyzer will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the analyzer software.

The schedule for the Electronice Simulator can be customized to meet local, state, or national accreditation requirements. A reminder message for the operator to run the external simulator can be set by the number of hours on the i-STAT Portable Clinical Analyzer and by the hours or tests on the i-STAT 1 Analyzer. The schedule for the automatic internal Electronic Simulator can be set by the number of hours on the i-STAT Portable Clinical Analyzer and by the hours or tests on the i-STAT 1 Analyzer. For details and lockout options, see the Customization section of this manual.

Note: All analyzers that pass the Electronic Simulator test are equivalent. Therefore, any representative number of analyzers that pass the Simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, proficiency testing, and method comparison studies.

Relative Humidity

The Electronic Simulator test will fail if high humidity interferes with the measurements. Therefore it is not necessary to record humidity where the analyzers are in use.

Internal Simulator

When the specified time has elapsed since the last Electronic Simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted before the sample is tested, adding about 20 seconds to the testing cycle.

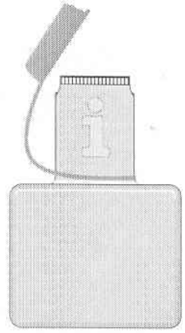
External Simulator

The external Electronic Simulator is a stable electronic device, which is inserted into the cartridge port. The test cycle for the external Electronic Simulator is about 60 seconds. (The test cycle for the internal simulator is shorter because it shares the initial part of the test cycle with the cartridge.)

Operating Characteristics

Operating Characteristics	
Dimensions	Height 1.9 cm Width 7.0 cm Length 9.0 cm
Weight	85 g
Operating Temperature	Same as Analyzer being tested
Operating Ambient Humidity	0-90% RH non-condensing (as shipped)
Storage Temperature	-20-50°C (-4-122°F)

Even when the internal Electronic Simulator is enabled, an external Electronic Simulator is needed:



- to validate an internal simulator failure.
- to reset the internal simulator schedule if a simulator test might interrupt testing, such as in a CVOR.

  Note: CVOR = Cardiovascular Operating Room
- for on-demand testing at any time.
- to perform the thermal probe check.
- to access the Proficiency and Calibration Verification test paths on the i-STAT Portable Clinical Analyzer.

The external Electronic Simulator should be stored in the static-free box in which it is shipped and the blue cap should be replaced after each use to protect the contact pads.

Stored Result

The results of the Simulator test are stored as a distinct record in the analyzer and can be transmitted to the Central Data Station.

Use ...

Use of the Electronic Simulator is described further in the Quality Control section of this manual.

Cleaning the Simulator

Before cleaning, cover the connector area with the blue rubber boot. This will minimize the possibility of any cleaning fluid getting into the simulator housing, thus contaminating the internal circuitry.

Clean the simulator with a gauze pad moistened with any of the cleaning agents approved for the analyzer, listed on page 17-1 of this manual.

Rinse the simulator using another gauze pad moistened with water and dry. DO NOT IMMERSE THE SIMULATOR IN ANY FLUID, AT ANY TIME.

If the connector itself is contaminated, the user should contact their Support Representative and arrange to have the simulator returned.

i-STAT 1 DOWNLOADER 6

Function

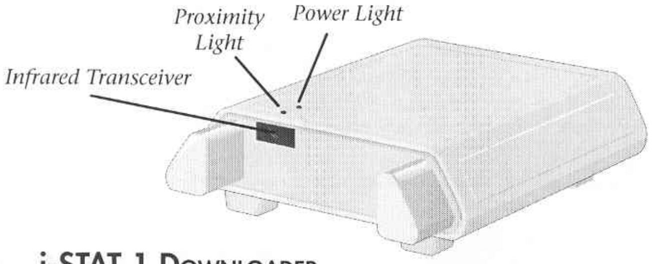
The Downloader converts infrared transmissions of test records from the analyzer to electrical form and transmits (uploads) them to the Data Manager. The Downloader also converts electrical signals from the Central Data Station to infrared transmissions, which are transmitted (downloaded) to the analyzer. Transmission is automatic when an analyzer is placed in a Downloader.

The Downloader comes in two formats:

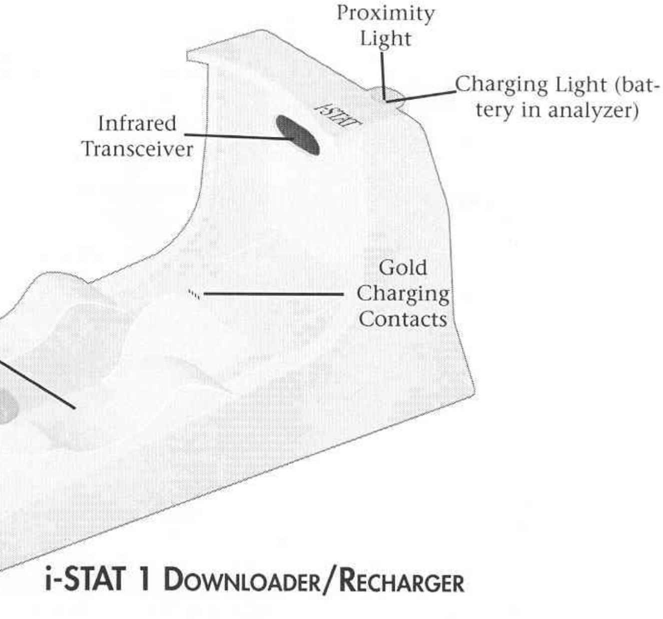
- ✧ Downloader: A low-profile table-top unit with "arms" between which the analyzer is placed, and
- ✧ Downloader/Recharger (DR): a cradle that the analyzer is placed within.

Both Downloader formats are available for use with direct wiring (serial format) or ethernet cabling (network format). Unless indicated otherwise, references to the Downloader apply to the Downloader/Recharger as well.

The Downloader/Recharger can recharge a rechargeable battery in the analyzer. If the analyzer contains a rechargeable battery, the battery begins recharging automatically as soon as the analyzer is placed in the Downloader/Recharger. The Downloader/Recharger also has a compartment for recharging a rechargeable battery outside the analyzer.


Proximity Light
Power Light
Infrared Transceiver

i-STAT 1 DOWNLOADER


Proximity Light
Charging Light (battery in analyzer)
Infrared Transceiver
Recharging Compartment
Gold Charging Contacts
External Battery Pack Charging Light

i-STAT 1 DOWNLOADER/RECHARGER

Specifications

Specification	Downloader	Downloader/Recharger
Size	5.25in (13.3cm) Wide 6.75in (17.2cm) Long 2.13in (5.4cm) High	4.12in (10.4cm) Wide 10.25in (26.cm) Long 5.00in (12.7cm) High
Weight	0.6 lbs (0.27kg)	1.2 lbs (0.55kg)
Power	AC-DC power adapter or PC/Downloader adapter. Input 12V ⎓	AC-DC power adapter or PC/Downloader adapter.* Input 12V ⎓
Operating Temperature	0 to 40°C 32 to 104°F	0 to 40°C 32 to 104°F
Storage Temperature	-20 to 50°C -4 to 122°F	-20 to 50°C -4 to 122°F
Pollution Degree (Allowable ambient pollution level)	2	2
Installation Category (Allowable overvoltage specification)	2	2
Communication To Central Data Station and other equipment	Serial (RS232), or Ethernet	Serial (RS232), or Ethernet
Communication Link To and From Analyzer	Infrared Transceiver	Infrared Transceiver
Indicator LEDs		
Power	Green	NA
Proximity	Red	Blue
Charge	NA	Red/Green
Configuration	By host computer	By host computer

Power Supply

Specification	Downloader and Downloader/Recharger
Input	100 - 240V~ 47 - 63 Hz .9 - .5A
Output	12V⎓ 3A max

* Recharge feature cannot be used in this configuration.

Running Cartridges in an Analyzer Docked in a Downloader/Recharger

All current i-STAT Cartridges may be run in an analyzer that is docked in a Downloader/Recharger.

Downloader/Recharger Indicator LEDs

Analyzer Battery LED (near top of Downloader/Recharger)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging
SPARE BATTERY (near middle of Downloader/Recharger)	
Off	No Rechargeable Battery
Green	Trickle Charging

Power Requirements

The Downloaders require one power outlet. The Downloader and Downloader/Recharger must be used with the AC power supply adapter supplied with them. The Downloader and Downloader/Recharger have different power supply adapters that are not interchangeable. The Downloaders are capable of supplying power to the portable printer which reduces the number of power outlets required in the downloading and printing area.

DR Affect on Ambient Operating Temperature Range

The operating temperature for an i-STAT 1 Analyzer is 18°C to 30°C. The DR and Rechargeable Battery may raise the temperature of the i-STAT 1 Analyzer 2°C-3°C relative to the ambient temperature if:

- The Analyzer is frequently lifted and replaced into the DR
- Multiple thermally controlled cartridges are run in the Analyzer while it is in the DR.

Programming and Connections

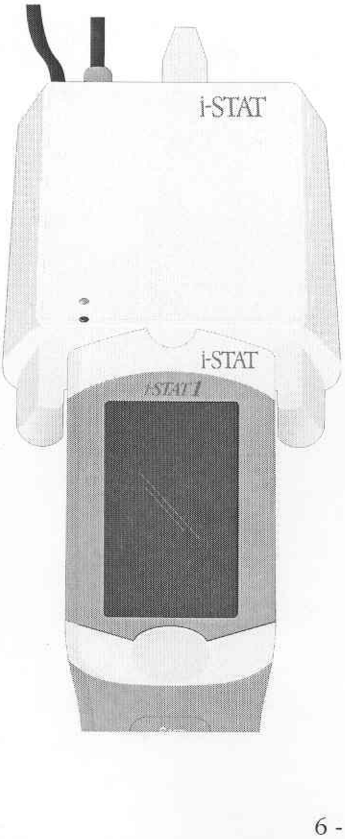
Details for programming the Network Downloaders can be found in the Downloader Programming and Wiring section of this manual. Diagrams and instructions for connecting peripheral components to the Downloader can also be found in the Downloader Programming and Wiring section.

Cautions

Do not place metal objects on or near the exposed gold charging contacts.

Be sure to install all cables and power supplies so they do not pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as the disconnect device for the Downloader and Downloader/Recharger and, therefore, the socket outlet must be installed (or located) near the Downloader or Downloader/Recharger and must be easily accessible.

Non i-STAT provided equipment connected to the network downloader's DB9 port must be isolated from earth ground.

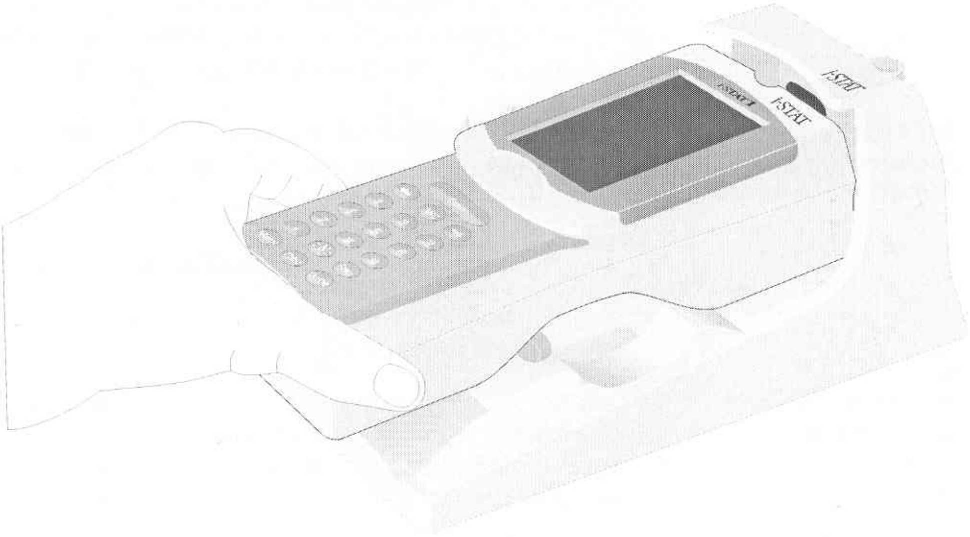


Transmitting Data from Downloader to the Data Manager

To transmit through a Downloader to the Data Manager, place the analyzer between the arms on the front of the Downloader with the test strip port end touching the Downloader. When properly aligned the red proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.

Transmitting Data from Downloader / Recharger to the Data Manager

To transmit data through a Downloader/Recharger, place the analyzer in the Downloader/Recharger's cradle. When properly aligned, the blue proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.



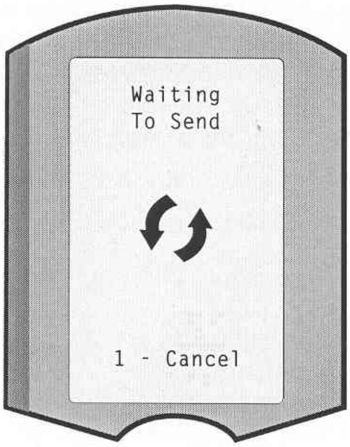
Transmitted Information

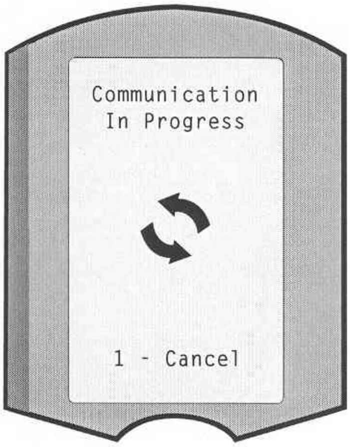
The following information is transmitted from the analyzer with each test record:

- The date and time the test was performed
- Operator ID and Patient ID or Quality Test fluid lot number
- All information entered by the operator, such as lot numbers, sample type and comment codes
- Result(s)
- Serial number of the analyzer
- Uses count of the analyzer
- Application software version in the analyzer
- Standardization software in the analyzer

Troubleshooting

The analyzer displays "Waiting to Send" until communication is established with the Central Data Station. When communication is established the message changes to "Communication in Progress" and the arrows circle until upload is complete. If the message does not change from "Waiting to Send" or if the Analyzer Status screen reports unsent results after the upload, refer to Support Services in the Troubleshooting section.


Waiting
To Send


Communication
In Progress

Charge Battery Before Use

Put new rechargeable battery in external charging bay on the i-STAT®1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable batteries may be placed on Downloader/Recharger to download data until rechargeable battery is ready.

Keep Battery Charged

Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either (1) keeping the rechargeable battery in an Analyzer that is periodically on the Downloader/Recharger, or (2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Rechargeable Battery Life

Rechargeable batteries normally exhibit reduced charge capacity after a reasonable lifetime or number of discharge-recharge cycles. i-STAT rechargeable batteries come with a service life expectancy of 15 months from the date of manufacture which appears on the battery. While the battery may last longer in your application, you may need to purchase a new rechargeable battery to replace a failing battery after the 15 month lifetime.

Charging the Rechargeable Battery

Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

Charging Rechargeable Battery in External Recharge Compartment

Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

STEP	ACTION
1	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2	To remove the battery after it is charged, back the pack out of the compartment.

Full recharge from a discharged state takes approximately 40 hours

Caution

If you are using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients. A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

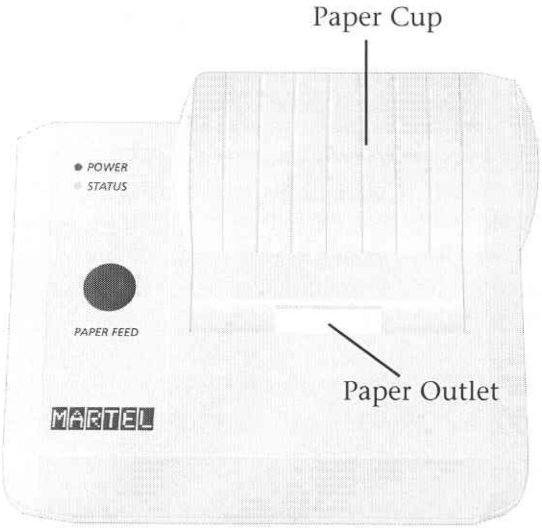
MARTEL PRINTER

Overview

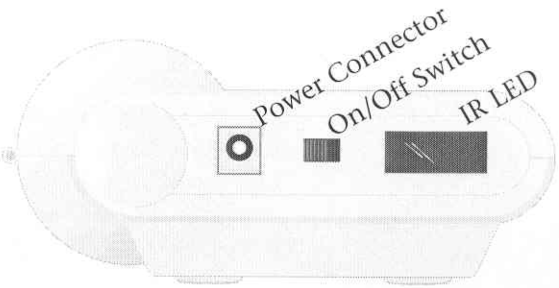
The printer can receive data directly from the analyzer via IR transmission or through a data cable connected to a Downloader. The printer can be recharged from a power adapter connected to an outlet.

Specifications

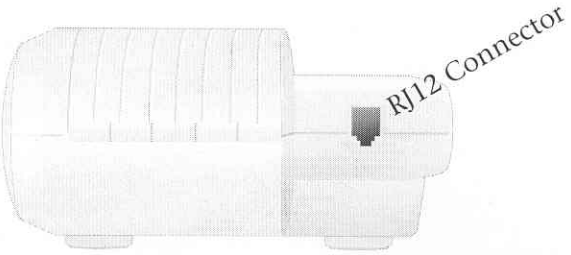
Dimensions	Height: 64mm Width: 135mm Depth: 130mm
Weight	425g (Approx.)
Power	1. 4.8V Nickle Metal Hydride battery pack. 2. Power adapter for AC outlet 3. Downloader
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Switch	On/Off
LED Indicator Lights	POWER: Green STATUS: Amber
Printing method	Thermal line printing
Printing speed	10 lines per second
Temperature	Operating: 0 °C to 50 °C (32-122°F) Storage: -20 °C to 60 °C (-4-140°F) Charging: 10 °C to 45 °C (50-113°F)


Paper Cup
POWER
STATUS
PAPER FEED
Paper Outlet
MARTEL

Top view of Martel Printer


Power Connector
On/Off Switch
IR LED

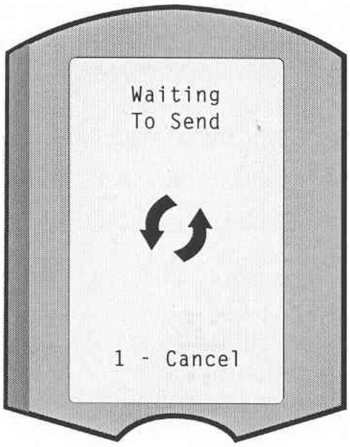
Side view of Martel Printer


RJ12 Connector

Back view of Martel Printer

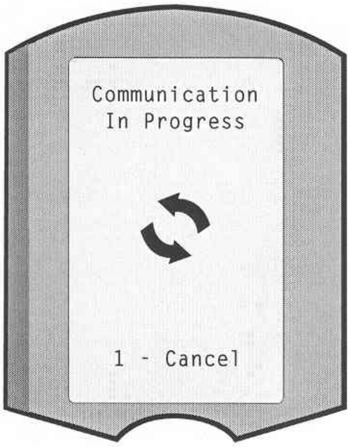
Troubleshooting

The analyzer displays "Waiting to Send" until communication is established with the Central Data Station. When communication is established the message changes to "Communication in Progress" and the arrows circle until upload is complete. If the message does not change from "Waiting to Send" or if the Analyzer Status screen reports unsent results after the upload, refer to Support Services in the Troubleshooting section.



Waiting
To Send

1 - Cancel



Communication
In Progress

1 - Cancel

Charge Battery Before Use

Put new rechargeable battery in external charging bay on the i-STAT®1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable batteries may be placed on Downloader/Recharger to download data until rechargeable battery is ready.

Keep Battery Charged

Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either (1) keeping the rechargeable battery in an Analyzer that is periodically on the Downloader/Recharger, or (2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Rechargeable Battery Life

Rechargeable batteries normally exhibit reduced charge capacity after a reasonable lifetime or number of discharge-recharge cycles. i-STAT rechargeable batteries come with a service life expectancy of 15 months from the date of manufacture which appears on the battery. While the battery may last longer in your application, you may need to purchase a new rechargeable battery to replace a failing battery after the 15 month lifetime.

Charging the Rechargeable Battery

Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

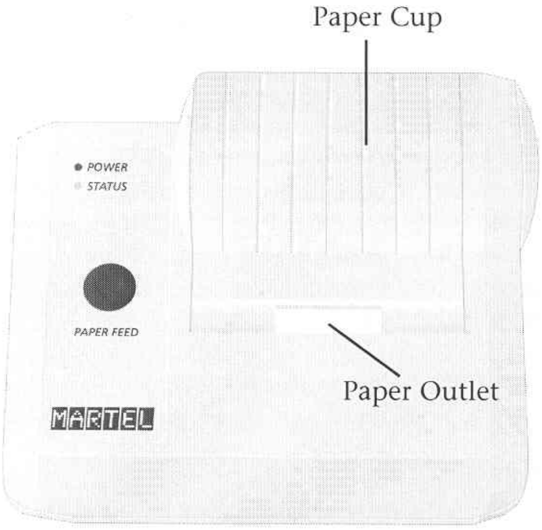
PORTABLE PRINTER 7

MARTEL PRINTER

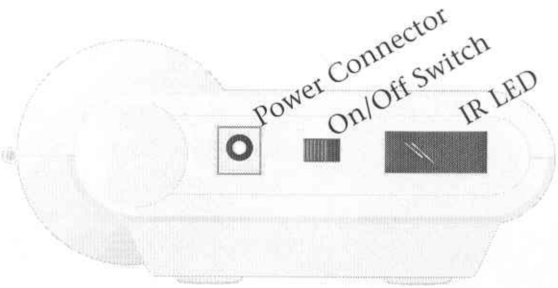
Overview The printer can receive data directly from the analyzer via IR transmission or through a data cable connected to a Downloader. The printer can be recharged from a power adapter connected to an outlet.

Specifications

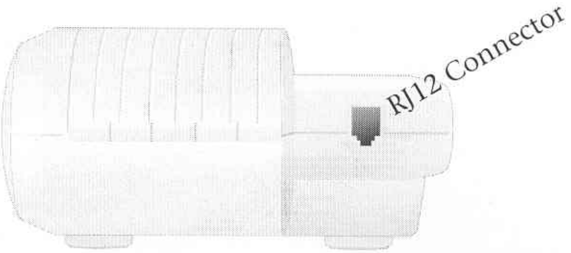
Dimensions	Height: 64mm Width: 135mm Depth: 130mm
Weight	425g (Approx.)
Power	1. 4.8V Nickle Metal Hydride battery pack. 2. Power adapter for AC outlet 3. Downloader
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Switch	On/Off
LED Indicator Lights	POWER: Green STATUS: Amber
Printing method	Thermal line printing
Printing speed	10 lines per second
Temperature	Operating: 0 °C to 50 °C (32-122°F) Storage: -20 °C to 60 °C (-4-140°F) Charging: 10 °C to 45 °C (50-113°F)


Paper Cup
POWER
STATUS
PAPER FEED
Paper Outlet
MARTEL

Top view of Martel Printer


Power Connector
On/Off Switch
IR LED

Side view of Martel Printer


RJ12 Connector

Back view of Martel Printer

Supplies Provided with Printer

- Adapter and power cord
- One roll of paper

Power

The printer is turned on using the switch on its left side. When the printer is on, the Power LED will be green. The plug for the AC adaptor is also on the left side.

For printer serial numbers below 240223657, the rechargeable battery is trickle charged when the printer is turned on or off and connected to an AC outlet. Before putting these serial number printers into use, the printer should be turned off and the battery charged for 16 hours.

For printer serial numbers above 240223657, the power LED may flicker when connected to the power supply and the switch is in the OFF position. This flicker indicates that the printer is fast charging. Fast charging occurs only when the printer is turned off. Trickle charging occurs when these printers are plugged in and turned on, but not in use. Printers above serial number 240223657 indicating low battery will charge to full capacity in 9 hours, if charged from a 12V supply with the power switch off.

The battery needs to be recharged for all printer serial numbers when the Status LED lights continuously during printing. If the battery becomes exhausted, printing will become faint, erratic, or not possible at all. Should this happen, turn the printer off and allow to recharge for 1 hour before attempting printing again

Paper

Paper may be ordered along with other supplies for the i-STAT System or paper with the following specifications can be used:

- Black print thermal paper
- 2.25" (5.7 cm) wide by 80' (25 m) long
- Paper grade: TF50KS-E2C

The Status light will flash to indicate that the paper has run out.

To replace the paper, open the paper cup lid by squeezing the lid as shown in the illustration and remove any remaining paper by pressing the Paper Feed button. **Do not pull paper through the printer mechanism.** Reel off a few centimeters from a new roll of paper and check that the end has clean straight edge. Slide the leading edge of the paper through the paper entry slot, with the leading edge of the paper feeding forwards from the bottom of the roll, until you feel resistance. Press the paper feed button and feed the paper through the printer mechanism. Keep the paper feed button depressed until enough paper is fed through the printer mechanism to pass through the paper exit slot. Sit the new paper roll in the paper cup and close the lid.

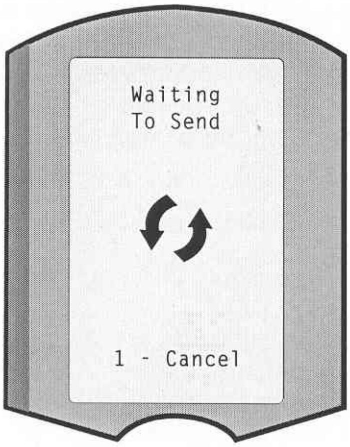
Should the paper become creased or out of line when feeding a new roll, cut the end off the paper roll, feed out the creased paper using the Paper Feed button, and reload ensuring the paper has a clear straight edge.

Before use, open the paper cup lid and ensure that the paper roll is present. Close the lid, ensuring that the paper passes through the paper exit slot. Turn the printer on. The Power indicator will light and the printer mechanism will reset.

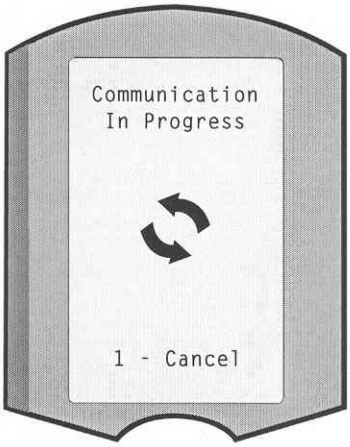
Position of paper roll in printer

Troubleshooting

The analyzer displays "Waiting to Send" until communication is established with the Central Data Station. When communication is established the message changes to "Communication in Progress" and the arrows circle until upload is complete. If the message does not change from "Waiting to Send" or if the Analyzer Status screen reports unsent results after the upload, refer to Support Services in the Troubleshooting section.



Waiting
To Send



Communication
In Progress

Charge Battery Before Use

Put new rechargeable battery in external charging bay on the i-STAT®1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable batteries may be placed on Downloader/Recharger to download data until rechargeable battery is ready.

Keep Battery Charged

Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either (1) keeping the rechargeable battery in an Analyzer that is periodically on the Downloader/Recharger, or (2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Rechargeable Battery Life

Rechargeable batteries normally exhibit reduced charge capacity after a reasonable lifetime or number of discharge-recharge cycles. i-STAT rechargeable batteries come with a service life expectancy of 15 months from the date of manufacture which appears on the battery. While the battery may last longer in your application, you may need to purchase a new rechargeable battery to replace a failing battery after the 15 month lifetime.

Charging the Rechargeable Battery

Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

PORTABLE PRINTER 7

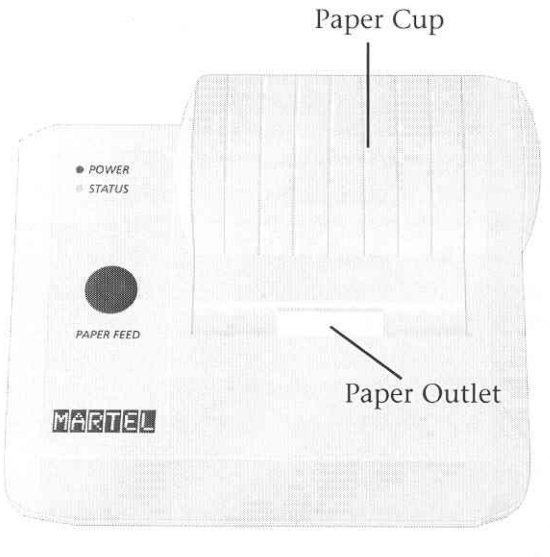
MARTEL PRINTER

Overview

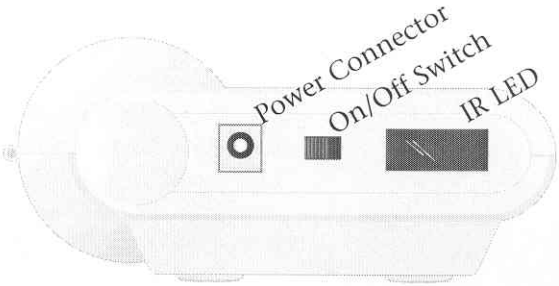
The printer can receive data directly from the analyzer via IR transmission or through a data cable connected to a Downloader. The printer can be recharged from a power adapter connected to an outlet.

Specifications

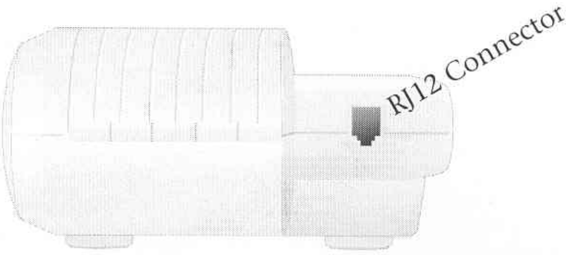
Dimensions	Height: 64mm Width: 135mm Depth: 130mm
Weight	425g (Approx.)
Power	1. 4.8V Nickle Metal Hydride battery pack. 2. Power adapter for AC outlet 3. Downloader
Communication Link	1. Infra-red 2. RJ12
Paper	5.7cm thermal
Switch	On/Off
LED Indicator Lights	POWER: Green STATUS: Amber
Printing method	Thermal line printing
Printing speed	10 lines per second
Temperature	Operating: 0 °C to 50 °C (32-122°F) Storage: -20 °C to 60 °C (-4-140°F) Charging: 10 °C to 45 °C (50-113°F)


Paper Cup
POWER
STATUS
PAPER FEED
Paper Outlet
MARTEL

Top view of Martel Printer

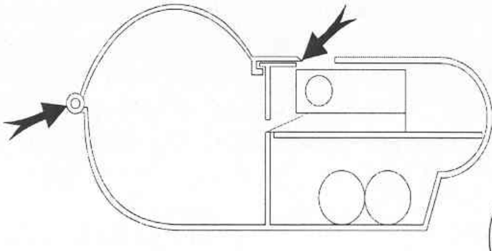

Power Connector
On/Off Switch
IR LED

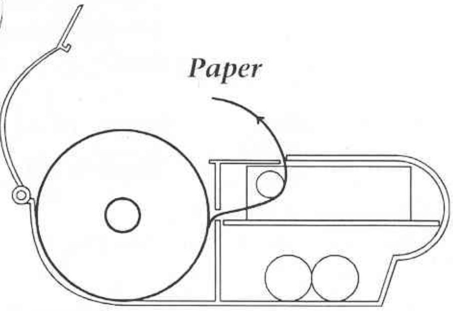
Side view of Martel Printer


RJ12 Connector

Back view of Martel Printer

Squeeze cup lid to gain
access to paper roll

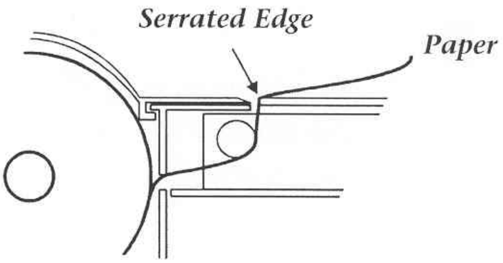




Position of paper roll in printer

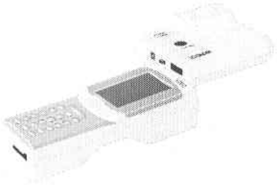
When removing a printout from the printer, pull the printout toward the front of the printer and tear from one side to the other across the serrated edge.

Using serrated edge
to tear paper



Printing Directly from the Analyzer

Before printing ensure that the printer is turned on. The printer is turned on and off using a switch on the left side of the printer. When the printer is on the Power LED will be green.



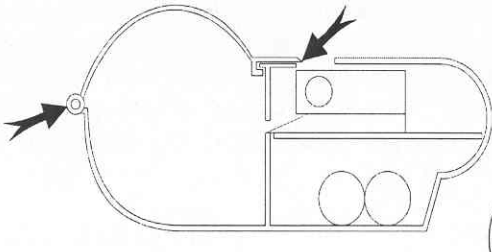
To print directly from the analyzer, point the analyzer's Infrared Communication Window at the printer's IR LED window on its left side, ensure that the results to be printed are displayed, and press the Print key on the analyzer. The printer must be within 1 to 5in. (2.5 to 12.7cm) of the analyzer and must not be too close to the analyzer. Do not move the analyzer or printer until printing is complete.

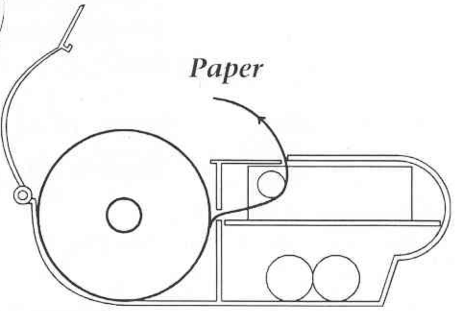
Printing Via a Downloader

See the Downloader Wiring and Programming section of this manual for directions to connect the printer to a Downloader or Downloader/Recharger. Before printing ensure that the printer is turned on. The printer is turned on and off using a switch on the left side of the printer. When the printer is on the Power LED will be green.

Place the analyzer between the arms of the Downloader or in the Downloader/Recharger, ensure that the results to be printed are displayed, and press the Print key. Do not move the analyzer or printer until printing is complete.

Squeeze cup lid to gain
access to paper roll

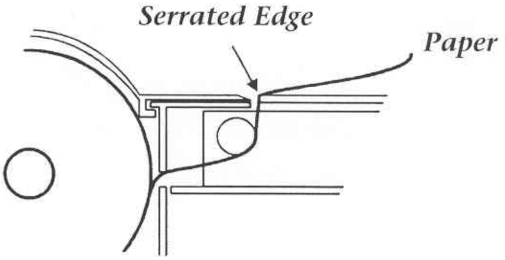




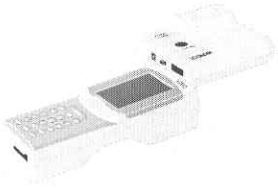
Position of paper roll in printer

When removing a printout from the printer, pull the printout toward the front of the printer and tear from one side to the other across the serrated edge.

Using serrated edge
to tear paper



Printing Directly from the Analyzer



Before printing ensure that the printer is turned on. The printer is turned on and off using a switch on the left side of the printer. When the printer is on the Power LED will be green.

To print directly from the analyzer, point the analyzer's Infrared Communication Window at the printer's IR LED window on its left side, ensure that the results to be printed are displayed, and press the Print key on the analyzer. The printer must be within 1 to 5in. (2.5 to 12.7cm) of the analyzer and must not be too close to the analyzer. Do not move the analyzer or printer until printing is complete.

Printing Via a Downloader

See the Downloader Wiring and Programming section of this manual for directions to connect the printer to a Downloader or Downloader/Recharger. Before printing ensure that the printer is turned on. The printer is turned on and off using a switch on the left side of the printer. When the printer is on the Power LED will be green.

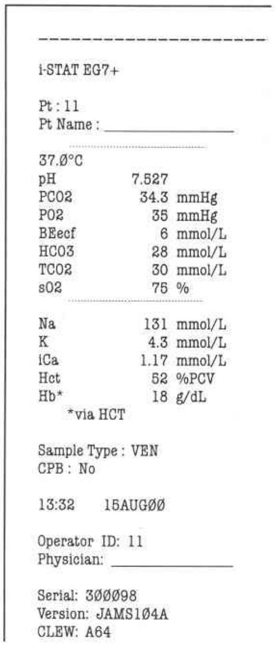
Place the analyzer between the arms of the Downloader or in the Downloader/ Recharger, ensure that the results to be printed are displayed, and press the Print key. Do not move the analyzer or printer until printing is complete.

Printing Many Results

Select 2 – **Data Review** from the Administration Menu on the analyzer, then select 7 – **List**. Use the arrow keys to page up and down through the pages of stored results. Press the numbered key for each test record to be printed. To deselect a record, press that numbered key again. When all test records have been selected, align the printer and analyzer according to the directions under Printing Directly from an Analyzer or place the printer in a Downloader or Downloader/Recharger according to the directions above, and press the Print key.

What is Printed

Name of Test	i-STAT cartridge type or PCx Glucose Strip
Sample ID	Patient ID or type of quality test and lot number of solution tested
Results	Results are printed with units as well as flags and comment codes if applicable.
At Patient Temperature	If the patient's temperature was entered on the Chart Page, a second set of results is displayed for blood gases at the patient's temperature.
Sample Type	Sample type selected from Chart Page when sample is patient or proficiency test
Free Fields	Information entered into the free fields on the Chart Page when sample is patient or proficiency test
Time and Date	Time and Date when test was performed
Operator ID	Operator ID
Lot Number	Lot number of cartridge or test strip if applicable
Serial	Serial number of the analyzer
Version	Analyzer application software
CLEW	Standardization software



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i-STAT EG7+

Pt : 11
Pt Name : ____________

37.0°C
pH          7.527
PC02         34.3  mmHg
P02            35  mmHg
BEecf           6  mmol/L
HC03           28  mmol/L
TC02           30  mmol/L
s02            75  %

Na            131  mmol/L
K             4.3  mmol/L
iCa          1.17  mmol/L
Hct            52  %PCV
Hb*            18  g/dL
     *via HCT

Sample Type : VEN
CPB : No

13:32     15AUG00

Operator ID: 11
Physician: ____________

Serial: 300098
Version: JAMS104A
CLEW: A64
```

Caution

- ✧ Use power supply provided with printer.
- ✧ Do not operate the printer without paper.
- ✧ Do not allow the power supply to become a trip hazard.
- ✧ Do not disturb the analyzer or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and analyzer or replace the analyzer in the Downloader to resume printing. Note: If significant time has elapsed, some results may be missing from the printout. Reprint the results.
- ✧ If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the analyzer. If the results do match, the patient sample should be retested using another cartridge. If they do not match, reprint the results. If the reprint still does not match the analyzer data, the printer requires service and the printed results must not be used.

Troubleshooting

Printer not printing. Power LED on and Status LED off:

- ✧ check that results are displayed or that results have been selected from List under Data Review.
- ✧ check that that distance between analyzer and printer, if printing directly from the analyzer, is not too short or too long.
- ✧ perform printer self test to ensure that printer is functioning. Turn the printer on while pressing the Paper Feed button, then release the Paper Feed button and ensure that the printout is clear.

Paper is feeding but nothing is printed: check that the paper is feeding from under the roll.

Printer not printing and Status light on continuously: battery needs to be recharged.

Printer Power LED does not come on when printer turned on: battery needs to be recharged. The power adapter cannot supply sufficient for printing so the battery needs to be partially charged before printing is possible.

Printer not printing and Status light flashing at rate of 0.5 seconds: printer is out of paper.

Printer not printing and Status light flashing at rate of 0.25 seconds: print head temperature too hot. Printing will be suspended until print head temperature returns to normal level.

DATA MANAGEMENT 8

Introduction

The i-STAT System provides comprehensive data management capabilities to ensure that blood analysis results obtained at the patient bedside can be integrated into the hospital's various information systems. The Data Manager computer system is capable of receiving simultaneous transmissions from several different types of blood analysis instruments. The instruments may include, but are not limited to:

- i-STAT Portable Clinical Analyzer (PCA)
- I-STAT-1 Analyzer
- AccuData GTS
- Phillips Blood Analysis Module via the Clinical Data Server

This section describes the information management capabilities of the i-STAT System and how the components can be integrated to meet the needs of point-of-care data management.

Components

The i-STAT 1 Analyzer

With each cartridge use, the analyzer allows entry of:

- operator identification number
- patient identification number
- proficiency identification number
- simulator serial number
- cartridge lot number
- glucose strip lot number (if applicable)
- control lot number
- calibration verification lot number
- comment codes for patient and control results
- chart page information
  - sample type
  - patient temperature
  - FIO_2
  - free fields: three fields, up to 9 characters each

The Portable Clinical Analyzer

With each cartridge use, the analyzer allows entry of:

- ☐ operator identification number
- ☐ patient identification number
- ☐ chart page information
  - patient temperature
  - FIO_2
  - free fields: three fields, up to 6 characters each
  - sample type

The analyzer electronically attaches its serial number, the test date, and test time to the results.

The Data Manager

A validated and qualified Data Manager computer system may be purchased from i-STAT Corporation for use with the Central Data Station 5 software application. The end user also has the option to purchase the computer system from another hardware vendor. In those cases, i-STAT Corporation will provide a minimum requirement specification to ensure proper operation and functionality of the Central Data Station 5 software application.

i-STAT Corporation and its distributors can supply the following hardware:

- i-STAT Data Manager computer system and its peripherals
- IR Downloader (Serial and Network) and required components
- IR Link and required components

i-STAT Central Data Station Version 5 Software

This is i-STAT's primary data management application. It supports all blood analysis instruments mentioned above via a combination of serial and/or network communications.

Please see the "Central Data Station 5" section of this System Manual for additional information on installation, setup, and configuration of this application.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Records, Control Results, Calibration Verification Results, and Proficiency Results (external quality control).

Note: All data (regardless of type) downloaded from the Portable Clinical Analyzer and the Philips Blood Analysis Module will only appear in the Results Data Viewer.

Additional features include the ability to:

- ☐ view patient and quality results by patient identification number, operator identification number, date/time chronological order, location, department, or analyzer serial number.
- ☐ edit identification numbers associated with results (original numbers are automatically retained for reference)
- ☐ add comments to records
- ☐ send results (automatically or by manual selection) to another information system such as an LIS or HIS

- archive records
- export records to ASCII text files
- manage instruments
- manage operators
- manage inventory
- manage policy exceptions
- monitor operator competence
- monitor LIS entry exceptions
- monitor download compliance

Downloader and Downloader/ Recharger

The Downloader and Downloader/Recharger are available for use with ethernet cabling (network format) and direct wiring (serial format). The Network Downloaders convert serial data transmitted from the i-STAT 1 Analyzer via infrared transmission to TCP/IP, which then delivers the data to the Data Manager using the hospital's ethernet system.

Through a customizable feature, transmissions can be performed automatically when an analyzer is placed in the Downloader or Downloader/Recharger.

Please contact your i-STAT Support Representative for additional information related to specifications and configuration requirements for your facility.

IR Link

A Portable Clinical Analyzer communicates to the Data Manager via an Infrared Interface Link (IR Link). The IR Link converts infrared signals received from the analyzer to electronic signals, and passes them to the Data Manager. To transmit results, place an analyzer in the IR Link and press the star (*) key. A single IR Link can be used to collect results from a limitless number of Portable Clinical Analyzers, one at a time. Transmission time is usually less than 15 seconds.

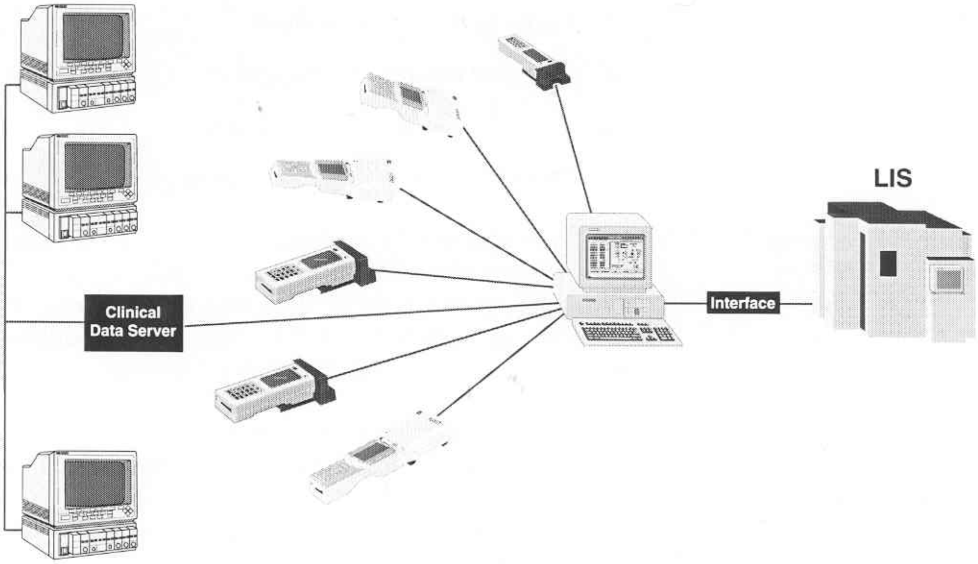
LIS/HIS Interface

The Data Manager typically connects to the Laboratory or Hospital Information System. The user can manually select records to send or the Central Data Station application can be configured to automatically transmit records to the alternate system as they are received. There are four data transmission protocols available:

- AME (US only): this protocol is used to simulate manual keystrokes when connected to a hospital's LIS or HIS. This protocol is installed and configured only by i-STAT Interface Operations department.
- ASTM: Data transmission conforms to ASTM E1381-95 and E1394-97 standards. Specifications for this protocol can be obtained from your i-STAT Support Representative.
- HL7: This is a robust Electronic Data Interchange (EDI) interface. Data transmission conforms to HL7 v2.4 and is based upon the CIC observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science (NCCLS) in the US under Document POCT-1-A. An activation key is required to use this protocol. Contact your i-STAT Support Representative to obtain this license key. This interface requires a receiver software from the LIS vendor.
- Data File: Formats the CDS file for third party use.

Standard Data Management Configuration

The figure below shows the standard i-STAT Data Management configuration. Downloaders, Downloader/Rechargers, and IR Links are placed in end-user departments and allow handheld analyzers to transmit results to the Data Manager. The results from the Philip Medical Systems Blood Analysis Module can also be interfaced via the Philips Clinical Data Server. The Data Manager then interfaces to the LIS/HIS.



Connecting Components

There is only one option available for physically connecting remote Downloaders, Downloader/Rechargers, and IR Links to a Data Manager. That option is:

- ☐ Ethernet Connection

  The i-STAT System connects terminal servers to Ethernet ports to allow a Local Area Network (LAN) or Wide Area Network (WAN) to transport data from a Downloader, Downloader/Recharger, or IR Link to the Data Manager using the TCP/IP protocol. Often, no additional wiring needs to be installed, but network ports or 'drops' may need to be installed in walls at appropriate locations. Also, power outlets will need to be available at each location in order to provide power to the Downloaders, Downloader/Rechargers or terminal servers. Using this method allows an unlimited number of Downloaders, Downloader/Rechargers, and IR Links to be connected to the Data Manager.

CUSTOMIZATION 9

Overview

This section describes the parameters that can be customized for site-specific testing requirements and the factory default settings. For the procedure to customize using the Central Data Station see the Central Data Station section of this manual. For the procedure to customize the analyzer directly through the keypad, see Customization in the i-STAT 1 Analyzer section of the manual. A customization profile consists of selections made from four major windows: Language, Unit Set, CLEW and Preferences. The Preferences Window consists of seven additional tabs: Instrument, ID Entry, Test, QC, Results, Analyte Enable, and Strip Lots.

Caution

Analyzers that have been repaired and returned or replaced will have the factory settings as indicated by the DEFAULT0 customization profile name on the Customization screen (under the Administration Menu) of the analyzer. These analyzers must be customized, if applicable, before being put into use. These analyzers will also have the current standard CLEW and application software (JAMS). If a different version of CLEW or application software is in use, it must be downloaded to these analyzers.

If location specific customization profiles are created, analyzers should not be moved from one location to another unless they are re-customized for the new location. This is especially important if "CPB Adjustment: Always" or "CPB Adjustment: Never" is included in a location-based customization profile. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery. If an analyzer customized for the CVOR as "CPB Adjustment: Always" is used for patients who are not on the pump, hematocrit results will be reported falsely high. If an analyzer customized as "CPB Adjustment: Never" is used for patients who are on the pump, hematocrit results will be reported falsely low. For details on the CPB function, see the Theory section of this manual.

ANALYZER CUSTOMIZATION OPTIONS AND DEFAULT SETTINGS

Option	Description	Default	Comments
LANGUAGE WINDOW	Language for text: English, Japanese, German, Italian, Dutch, Spanish, French, Swedish, Russian, Portuguese, Danish, and Finnish	English	Russian can be dowloaded only to the Portable Clinical Analyzer. Portuguese, Danish, and Finnish can be dowloaded only to the i-STAT 1 Analyzer.
UNIT SET WINDOW	Reporting units for results. Selected from predefined sets or by analyte.	Unit Set 00	See table below with 17 predefined unit sets. Unit Set 99 allows the name and units for each test to be defined individually. Note: Reference Ranges and Action Ranges in the Preferences Window must be changed when changing units.
i-STAT 1 ANALYZER AND PHILIPS BAM CLEW WINDOWS	Standardization data. All non-expired versions listed.		The CLEW software has an expiration date. If an expired CLEW remains in a customization profile, a warning will be displayed.
i-STAT 1 SOFTWARE WINDOW	JAMS functionality data.		Users can remotely request a JAMS update for an i-STAT 1 Analyzer from the CDS. See Section 18 (Updating the Software) for full details.
CHART PAGES	Feature allows users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings.	CHART0	See the "i-STAT 1 Analyzer Chart Page Customization" Technical Bulletin for full details.
PREFERENCES WINDOW	Options and default settings are listed under seven headings: Instrument, ID Entry, Test, QC, Results, Analyte Enable and, Strip Lots.		
USE OPERATOR LIST	4000 operator IDs can be stored in the analyzer along with certification start and end dates for both glucose test strip and cartridge testing.	Not enabled (no information stored)	Operator lists are created in the Operator Workspace on the Central Data Station. This check box cannot be enabled if the Operator List is empty in the Operator Workspace for all Departments (other than the one labeld "Unassigned").

Option	Description	Default	Comments
PASSWORD	0-5 digit password to access Set Clock, the Change function in Customization, and Utility under the Administration menu.	No password	Password protection for the Set Clock function can be enabled or disabled. See below.
DATE FORMAT	mm/dd/yy or dd/mm/yy	mm/dd/yy	For Clock Set function only.
INACTIVITY TIMEOUT	Number of seconds after a result is displayed and no operator intervention that an analyzer will turn off. Allowable range is 45 to 1620 seconds.	120 seconds	
SOUND	If enabled, the analyzer will emit a beep after each successful key press, when results are ready or when a Quality Check message is displayed.	Beep enabled	If Sound is disabled, the analyzer will only beep when a sample is accepted during glucose test strip testing and after a successful barcode entry.
AUTO TRANSMIT	Analyzer transmits results when placed in Downloader or Downloader/Recharger.	Enabled	
MEMORY FULL ACTION	Not enabled: over-write the oldest record without warning. Enabled: Warn user (start-up warning) or Lockout (testing disabled until upload occurs).	Not enabled	Memory Full refers to when the unsent records as recorded on the Analyzer Status screen reaches 5000. Uploading does not erase the data from the analyzer's memory.
BATCH MODE TIMEOUT	Not active at this time.		
DISPLAY PASSWORD FOR CLOCK PAGE	The default setting is enabled. However it may be useful to disable password protection for the clock page in the Spring and Fall when clocks are set forward and backward one hour.	Enabled	
ENABLE PCX GLUCOSE	Enables the PCx glucose test strip reader on the i-STAT1 Analyzer.	Not Enabled	When glucose test strip testing is disabled, the analyzer does not display any options for the PCx Glucose Test Strip.
SYNCHRONIZE CLOCK TO CDS	Will synchronize or update the real time clock in the i-STAT1 Analyzer to the Central Data Station's clock at the time of each download.	Not Enabled	This eliminates the need to reset the analyzer's clock at the beginning and end of Daylight Savings Time.
APPLY OPERATOR LIST TO VIEWING STORED PATIENT RECORDS	Requires operator to enter their operator ID number to access stored patient results on the i-STAT1 analyzer.	Not Enabled	This option can help a facility comply with patient privacy regulations.
LIMIT NUMBER OF RECORDS IN TRANSMIT ALL	Allows the user to apply a date range limit to the Transmit All function in the i-STAT1 Analyzer	Not Enabled	This will prevent operators from sending older patient records that may have already been deleted from the Central Data Station.
UPLOAD SCHEDULE	Options are Off, or every X hours, where X can be 1 to 65535 hours. If enabled, the behavior of the analyzer if the schedule is not met can be specified. Behavior Options are: Warn User (start-up warning message) or Lockout (testing disabled until upload occurs).	Off: no warning or lockout.	If no upload schedule is specified and the Memory Full warning is ignored and Auto-transmit disabled, data will eventually be overwritten. However, if an analyzer has not been used and the upload interval is exceeded, this analyzer will be inoperable if the lockout option is used.

PREFERENCE WINDOW: for Operator and Patient ID Options

Option	Description	Default	Comments
OPERATOR ID	Minimum and maximum allowed operator ID length (scanned or manually entered)	Min = 0 Max = 15	If operator IDs are a fixed length, the min. and max. settings should both be equal to the ID length.
REPEAT ID ENTRY	Operator must enter ID twice. Analyzer prompts operator to start again if IDs do not match.	Enabled: repeat required	This option can be set for manual and/or scanned ID Entry.
INCLUDE ID ON PRINTOUT	Enables/Disables printing of operator IDs on printouts from the Martel printer.	Enabled	Disabling the printing of operator IDs can prevent uncertified operators from learning the IDs of certified operators.
BARCODE OPTIONS	The type of barcodes used for Operator ID. See table below.	All barcode types	
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.	None	Check digit algorithms are given in HL7 Specification, Section 2.9.5.3
INVALID OPERATOR	Behavior of analyzer when Operator ID not in stored list or certification date expired Options are: Not enabled (continue without warning), Warn User (prompt to continue), and Lockout (block testing until a valid Operator ID is scanned/entered).	Continue without warning	This option should not be enabled if the Use Operator List option is disabled. Separate Actions can be chosen for Certification Expired or Operator Not On List.
PATIENT ID	Minimum and maximum allowed patient ID length (scanned or manually entered)	Min = 0 Max = 15	If ID numbers are a fixed length, the min. and max. settings should both be equal to the ID length.
REPEAT ID ENTRY	Operator must enter patient ID twice. Analyzer prompts operator to start again if IDs do not match.	Repeat ID enabled	This option can be set for manual and/or scanned ID entry.
PATIENT ID RECALL	Operator can recall last patient ID when analyzer prompts for Patient ID.	Enabled	The most recent patient ID is recalled by pressing the → key.
BARCODE OPTIONS	The type of barcodes used for Patient ID. See table below.	All barcode types	
MANUAL ENTRY CHECK DIGIT	Options are None, ISBN Modulus 11 Check, and IBM Modulus 10 Check.	None	Check digit algorithms are given in HL7 Specification, Section 2.9.5.3

Option	Description	Default	Comments
AUTO-CHART PRESENTATION	If enabled, the Chart page will be displayed automatically. There are separate selections for cartridge and test strip tests.	Not enabled: operator must press the → key to display the Chart page.	If any information on the Chart page is mandatory for the site, Auto-Chart Presentation is recommended.
CARTRIDGE PATIENT TEST	Require information before running cartridge: Operator will be required to enter Operator and Patient IDs before the analyzer will initiate a cartridge test cycle. Enter Lot Number: Adds a Cartridge Lot Number prompt to the cartridge test cycle. If the option above is enabled along with this option, the operator will be required to enter the cartridge lot number before the analyzer will initiate a patient test cycle. Scan Cartridge Barcode: requires the user to scan the cartridge Lot number barcode before entering an operator and patient ID after a cartridge has been inserted into an i-STAT 1 Analyzer. Third Party Result Output and Require Analyzer to be in Downloader: These two options were instituted for the release of the new RIBS data integration feature. Please see the "RIBS Feature for the i-STAT System" Technical Bulletin for full details. **These options SHOULD NOT be activated by users until the data integration process is complete, as misconfiguring your analyzers using these new features can cause testing to be disabled.**	Not enabled	This option is referred to as "Information First" in the Procedure for Cartridge Testing section. When not enabled, the operator can insert a cartridge and the test cycle will initiate. Information is then entered during the test cycle. Cartridge lot numbers are mandatory prompts for tests performed under Quality Tests. The Scan Cartridge Barcode option is required for i-STAT's immunoassays.
PATIENT TEST COMMENT CODE	Options are: No prompt or prompt as follows: • Prompt for Comment Code, All Results in Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • Prompt for Comment Code, Any Result out of Range (action range). Comment Code can be optional (Allow no Comment) or mandatory (Require Comment). • A comment code of up to 3 characters is allowed.	No prompt	Care should be taken to select combinations that make sense. In the case of a missed required Comment Code, the results will be stored and "_ _ _" will be entered as the Comment Code.
SAMPLE TYPES FOR CARTRIDGE	Drop down menus for each sample type allow the six sample types to be re-ordered or changed. Up to 4 user-definable characters are allowed for each sample type.	1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR	The sample type is stored with the test record and is included on the printout from the portable printer and in the record in the Central Data Station.
CHART PAGE	Any item on the Chart Page can be deleted by clicking off the check mark in the Display column or be made mandatory by clicking a check mark in the Mandatory column. If any item is set as mandatory, the Chart Page will be displayed automatically after the Patient ID is entered. The items on the Chart page can also be rearranged by holding down the left mouse button and dragging the item to another location.	All items set to not mandatory.	
TEST STRIP PROMPT FOR SAMPLE TYPE	Options are: Prompt operator to choose between Art/Cap or Venous sample types or NO PROMPT with either Art/Cap or Venous as the default sample type.	Prompt	
ENABLE CUSTOM CHART PAGE	Allows users to customize the Chart Page on their i-STAT 1 Analyzers in order to capture user-defined information such as ventilator settings.	Disabled	See the "i-STAT 1 Analyzer Chart Page Customization" Technical Bulletin for full details.

PREFERENCE WINDOW: FOR QUALITY CONTROL OPTIONS – CARTRIDGE

Option	Description	Default	Comments
EXTERNAL SIMULATOR SCHEDULE	Options are Off (no prompt), an interval of specified hours (1 to 65535 hours), or an interval of specified patient tests (up to 99999). The behavior of the analyzer if the schedule is not met can also be specified: Warn or Lockout (testing disabled until Simulator used).	No prompt	For the quality control of i-STAT analyzers, i-STAT recommends the use of the Electronic Simulator. i-STAT's recommendation for the frequency of the Electronic Simulator is once every 24 hours. More frequent use or use according to number of patient tests may be required by accreditation and regulatory bodies.
INTERNAL SIMULATOR SCHEDULE	Time interval when the internal Electronic Simulator test will be run. Options are Off; an interval of specified hours (1 to 65535 hours); 8/24 (every 8 hours for blood gases, coagulation, hematocrit and immunoassays, and every 24 hours for other tests); an interval of specified patient tests (up to 99999). The behavior of the analyzer if the simulator test fails can also be specified. If the Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display "FAIL" on subsequent cartridges until the test passes. If Lockout is not selected, the simulator test will not be initiated again until next scheduled time.	Interval 24 hours. Lockout	

PREFERENCE WINDOW: FOR QUALITY CONTROL OPTIONS – TEST STRIP

Option	Description	Default	Comments
STRIP CONTROL SCHEDULE	Schedule options are: Off, Every X hours (1 to 65535 hours), Every X Patient Tests (0 to 255 tests), and up to three predetermined times daily The behavior of the analyzer if the schedule is not met can also be specified. Options are: Warn (start-up warning) or Lockout (disable test strip testing until QC run).	Off	
STRIP CONTROL TEST SETTINGS	Prompt or no prompt for Normal/(Mid)Level Control. Comment Code when a value is in-range. Options are: Disabled (no prompt for comment code), Allow no Comment (Comment Code optional), Require Comment. Comment Code when value is out of range. Options are: disabled (no prompt for Comment Code), Allow no Comment (Comment Code optional), Require Comment. A Comment Code of 3 characters is allowed.	No prompt for Normal/(Mid) Level Control and no prompt for Comment Code.	If selected, the prompt for the Normal Level control will come after the prompt for the Low Level control.

PREFERENCE WINDOW: FOR RESULTS REPORTING OPTIONS

Option	Description	Default	Comments
REFERENCE RANGES	Reference ranges can be defined for each test. The ranges will be depicted as tic marks on the bar graphs on the result pages. There are no bar graphs for blood gas, coagulation, and immunoassay tests.	Ranges listed in the Cartridge and Test Information sheets and the Precision PCx and PCx Plus Glucose Test Strip package insert.	Ranges will be displayed on the Customization screen of the analyzer under the Administration Menu. Only one range is allowed for each test in a particular analyzer. However, different customization profiles can be set up in specific analyzers used for specific patient populations. **Care should be taken to enter the same units as selected in the Unit Set Window.**
ACTION RANGES	High and low action ranges can be defined for each test (-99999.9 to 99999.9).	Disabled	**Care should be taken to enter Action Ranges within the reportable ranges of the tests.** **Care should be taken to enter the same units as selected in the Unit Set Window.** The action ranges for glucose apply to the cartridge and the test strip.
PRINT REFERENCE RANGES	Reference Ranges can be printed with results. Ranges will print only if the record to be printed is stored with the active Preference set in the analyzer.	Disabled	The active Preference set in the analyzer is listed as "Custom" on the Analyzer Status page and the Preference set stored with the record is displayed on the Chart Page when the record is recalled and is printed with the results.
OPERATOR TEST SELECTION	Requires the operator to select tests to be reported from a cartridge test panel.	Disabled	This option facilitates compliance with Medicare/Medicaid regulations in the USA.
ACT OPTIONS (i-STAT 1 Analyzer Only)	The user can select between the current 37° (PREWRM) result calibration and a new "NON-PREWARM" (ambient temperature) result calibration for both Celite ACT and Kaolin ACT cartridges.	PREWRM for both cartridge types.	Pleas see the Technical Bulleti "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT 1 Analyzer" for full discussion.
HEMATOCRIT OPTIONS	Reference anticoagulant used to calculate hematocrit result: K3EDTA or K2EDTA/Heparin/None. (NaEDTA is included in this option and None means no anticoagulant.) CPB options are: 1. **Prompt:** asks user whether to apply CPB compensation when cartridge includes hematocrit sensor. 2. **Never:** CPB correction is never applied when running a cartridge with a hematocrit sensor.. 3. **Always:** apply CPB correction every time it runs a cartridge with a hematocrit sensor.	K3EDTA Prompt CPB	See Theory section in this manual for explanation of CPB. Analyzers can be customized by location. Analyzers customized for "CPB: Always" should not be used for reporting Proficiency Testing results..
DECIMAL SEPARATOR	Select comma (,) or period (.)	Period	
BASE EXCESS CALCULATION	Select Base Excess of Extracellular Fluid (BEecf) or Base Excess of Blood (BEb).	BEecf	See Cartridge and Test Information sheet for PCO_2 for formulas.

PREFERENCE WINDOW: for Analyte Enable

Option	Description	Default	Comments
APPLY GLOBALLY	Test(s) can be disabled for all cartridge types. To enable/disable a particular analyte on all cartridge types, simply check/uncheck the box next to the analyte name in the Apply Globally section.	All tests enabled.	The global selection takes precedence over the cartridge type selection.
APPLY BY PANEL	Test(s) can be disabled for individual cartridge types. To enable/disable a particular analyte on a specific cartridge type, make sure the analyte is first checked under the Apply Globally section. Then click on the cartridge type under the Apply by Panel section, and then check/uncheck the box next to the analyte name.	All tests enabled for all cartridge types.	

PREFERENCE WINDOW: for Quality Control Options – Test Strip Lots

Option	Description	Default	Comments
TEST STRIP LOT NUMBERS	Up to 5 test strip lot numbers of 14 characters each can be entered. Upper and lower ranges for low, mid and high controls for each test strip lot can be entered.	Blank	Expired test strip lots must be manually deleted on the expiration date. If no control values are entered, the analyzer will use the control values programmed into the test strip lot number. If the Customization program is enabled (active), new lot numbers will be automatically added to the analyzer's memory when it is placed in a Downloader or Downloader/Recharger.
TEST STRIP LOT NOT ON LIST ACTION	Behavior of analyzer when a scanned/entered test strip lot is not on the test strip lot list. Options are: Disable (allow test to continue without warning); Warn (and prompt to continue); Lockout (disable testing until valid test strip lot number is scanned/entered).	Disabled	

PREFERENCE WINDOW: FOR BARCODES

Option	Description	Default	Comments
ID BARCODES *	The user can select any or all of the following as valid barcode formats for both the operator and patient ID: • I2 of 5 • Code 128 • Codabar • Code 93 • Code 39 • EAN 8, EAN 13	All barcode types	Barcode type Code 128 will support USS 128 and UCC/EAN 128, but not ISBT 128.
I2 OF 5 OPTIONS	No Check Digit USS Check Digit OPCC Check Digit	USS Check Digit	
CODE 39 OPTIONS	Check Digit or No Check Digit Alphanumeric or Full ASCII	Check Digit, Full ASCII	
TRUNCATE DIGITS	User can select how to truncate digits from a scanned operator and/or patient ID: First: enter number of leading characters to be stripped from the barcode. Last: enter number of trailing characters to be stripped from the barcode.	No truncation	The analyzer will accept up to 15 characters for operator and patient IDs.

* **Note:** For fields other than Operator and Patient ID, only the default setting for the barcode type can be scanned. These are:

- Code I2 of 5 with USS Check Digit
- Code 39 Full ASCII with Check Digit

SAMPLE COLLECTION 10

SPECIMEN COLLECTION

Overview

The specimen used to fill a cartridge or apply to a test strip must be collected and handled properly to ensure that the results represent the patient's current status.

Only fresh whole blood samples are recommended for use with the i-STAT System.

Specimens should be collected according to the facility's policies and procedures. The following precautions (taken from the references at the conclusion of this section) can help avoid potential sources of error prior to filling a cartridge or applying sample to a test strip.

VENIPUNCTURE - GENERAL

Overview

Venipunctures are typically performed for:

- acid-base balance
- electrolyte studies
- metabolic studies
- coagulation studies
- hematologic studies

Observe the following precautions:

I.V. Line

Avoid drawing from an arm with an I.V. line. I.V. solutions will dilute the sample and may interfere with the tests.

Tourniquet

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid..

If a tourniquet is applied for more than one minute while looking for a vein, release and reapply after two to three minutes.

Allow the tourniquet to remain in place until all blood is withdrawn to prevent changes in ionized calcium and pH results.

Muscle Activity

Avoid extra muscle activity, such as clenching and unclenching the fist, which may increase potassium results.

Hemolysis

Avoid hemolysis (bursting of red cells) by

- allowing residual alcohol to dry over the puncture site
- discarding a sample from a traumatic draw.

Hemolysis will cause an increase in potassium results and a decrease in calcium results. For cTnI, CK-MB, and BNP cartridges, gross hemolysis can also cause a decreased alkaline phosphatase activity and an increased proteolytic activity, resulting in decreased detection of cTnI, CK-MB, or BNP.

Tube Order

Collect blood collection tubes in the prescribed sequence to avoid interference due to carry-over of additive from one tube to the next:

- No additive
- Citrate
- Heparin
- EDTA - Na_2, K_3 or K_2
- Oxalate, fluoride, iodoacetate

If a citrate tube is drawn, draw a 5mL plain discard tube before drawing the heparin tube.

VENIPUNCTURE - pH, PCO_2, ELECTROLYTE, CHEMISTRY, AND HEMATOCRIT TESTS

Anticoagulants

If the sample can be tested in a cartridge immediately, a plain syringe can be used. If a cartridge cannot be filled immediately the sample should be collected in a blood collection tube with sodium heparin or lithium heparin or a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium (such syringes contain balanced or low-level heparin). If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood. Blood collection tubes contain approximately 15 U/mL when filled to capacity.

Samples collected in EDTA anticoagulant may be used only with the i-STAT Glucose and BNP cartridges. It may be convenient to collect a single EDTA tube when testing for glucose and glycated hemoglobin (HbA1c) simultaneously. **EDTA may not be used with any cartridge type other than the Glucose or BNP cartridges.** EDTA will cause a clinically significant error in sodium, potassium, chloride and hematocrit results and may affect other chemistry tests. Do not use an EDTA sample with a cartridge that includes glucose as part of a panel. Even if only the glucose result is to be used, all results are stored in the analyzer's memory and, since results can be printed and transmitted to a Central Data Station, they can become part of the patient's permanent record.

i-STAT BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA. The use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes. The use of whole blood or plasma samples containing other anticoagulants such as heparin, oxalate, and citrate is not recommended.

i-STAT cTnI and CK-MB cartridges require the use of either:

1. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or
2. non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

   The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB readings.

i-STAT CHEM8+ cartridges require the use of:

1. whole blood collected in non-heparinized capillary tubes, evacuated tubes, or syringes, as long as sample is tested immediately upon draw,
2. heparinized whole blood collected in balanced heparin syringes or capillary tubes, or
3. heparinized whole blood collected in evacuated tubes containing lithium or sodium heparin, as long as the tubes are filled to capacity.

Fill Requirements

Fill blood collection tubes with *and without* anticoagulant and syringes with anticoagulant to capacity. Incomplete filling of anticoagulated tubes and syringes will cause higher heparin-to-blood ratios, which will decrease ionized calcium results and may affect other results. Under filling blood collection tubes with *and without* anticoagulant may also cause decreased PCO_2 , HCO_3 and TCO_2 results.

Partial-draw blood collection tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL), with *or without* anticoagulant, are not recommended for blood gas or CHEM8+ cartridge analysis because of the potential for decreased PCO_2 , HCO_3 and TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

When drawn into an evacuated tube containing heparin (for cTnI or CK-MB testing) or EDTA (for BNP testing), samples should not be used unless the blood collection tube is at least half full.

Mixing

Gently mix blood (whether anticoagulated or not) immediately to avoid clotting. Invert a blood collection tube at least 10 times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1.0 cc syringe.

Exposure to Air

Avoid exposing the sample to air when testing venous samples for ionized calcium, pH, PCO_2 and TCO_2. Test immediately if the sample is drawn into a blood collection tube. Expel any air bubbles immediately if the sample is drawn into a syringe or leave an air bubble next to the plunger and do not allow it to move through the sample.

Time to Test

For the most accurate results, test samples immediately after drawing. Samples for lactate must be tested immediately. Samples for pH, $P\text{CO}_2$, $P\text{O}_2$, TCO_2, and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.

If testing is not immediate, remix blood collection tubes by gentle inversion at least 10 times. Roll syringes between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, and then discard the first two drops of blood. Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note It may be difficult to properly remix a sample in a 1.0 cc syringe

VENIPUNCTURE - COAGULATION TESTS

Blood Flow

Collection technique resulting in good blood flow must be used. Inadequate blood flow may produce erroneous results.

Plastic

The sample for testing should be drawn into a **plastic** collection device (syringe or blood collection tube) containing **no anticoagulant, clot activators, or serum/plasma separators**. Any transfer device (dispenser, capillary tube, pipette or syringe) **must be plastic** and must **not contain anticoagulant**.

Samples collected into glass tubes or syringes, or in tubes containing anticoagulants, activators, or separators cannot be used with the i-STAT coagulation cartridges.

Note: CLSI guidelines recommend that the sample for coagulation testing be the second or third tube drawn when using a blood collection system (use a discard tube if this is the only sample being drawn) or be taken from the second syringe if a double syringe technique is used for drawing blood.

Time to Test

The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.

Repeat Test

If a repeat measurement is needed, a fresh sample must be obtained.

VENIPUNCTURE - GLUCOSE TEST STRIP (i-STAT®1 ANALYZER)

Anticoagulant

Use only fresh whole blood samples. Collect the venous blood sample in a collection tube containing sodium heparin, lithium heparin or EDTA ensuring that the tube is completely filled. Invert the tube with the sample several times immediately before removing the sample. Use a disposable transfer pipette to obtain a sampe from the center of the collection tube.

Time to Test

Apply a drop of blood directly to the target area on the test strip, covering the entire area. Test within 30 minutes of collection.

ARTERIAL PUNCTURE - GENERAL

Overview

Arterial punctures are performed to access gas exchange status.

PCO_2, PO_2, and pH values change with changes in ventilatory support at a rate dependent on underlying conditions. Sample should be drawn after these changes have stabilized.

ARTERIAL PUNCTURE - BLOOD GAS, ELECTROLYTE, CHEMISTRY, AND HEMATOCRIT TESTS

Evacuated Tubes

Evacuated or other blood collection tubes are not recommended for blood gas analysis.

Syringes and Anticoagulant

If the sample can be tested in a cartridge immediately, a plain syringe can be used.

If a cartridge cannot be filled immediately, the sample should be collected in a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium (such syringes contain balanced or low-level heparin).

If manually heparinizing syringes, the heparin-to-blood ratio should not exceed 10 U heparin per milliliter of blood.

Fill syringes to the recommended capacity or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under filling syringes will cause higher heparin-to-blood ratios which will decrease ionized calcium results due to binding. Under filling syringes with liquid heparin will also dilute the sample causing results to be affected.

i-STAT BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA. The use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes. The use of whole blood or plasma samples containing other anticoagulants such as heparin, oxalate, and citrate is not recommended.

i-STAT cTnI and CK-MB cartridges require the use of either:

1. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or
2. non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

   The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI or CK-MB readings.

i-STAT CHEM8+ cartridges require the use of:

1. whole blood collected in non-heparinized capillary tubes, evacuated tubes, or syringes, as long as sample is tested immediately upon draw,

2. heparinized whole blood collected in balanced heparin syringes or capillary tubes, or
3. heparinized whole blood collected in evacuated tubes containing lithium or sodium heparin, as long as the tubes are filled to capacity.

Mix

Mix blood (whether anticoagulated or not) by rolling between the palms for at least 5 seconds, each in two different directions. Then invert the syringe repeatedly for at least 5 seconds. Discard the first 2 drops of blood.

Exposure to Air

Avoid or remove immediately any air drawn into the syringe and maintain anaerobic conditions.

Time to Test

For the most accurate results, test samples immediately after draw. Samples for lactate must be tested immediately. Samples for pH, $\boldsymbol{P}CO_2$, $\boldsymbol{P}O_2$, TCO_2, and ionized calcium should be tested within 10 minutes. Other analytes should be tested within 30 minutes.

If testing is not immediate, remix the syringe by rolling between the palms for 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Blood in the tip of the syringe may have been exposed to air and may not be homogenous with the sample in the barrel of the syringe. Note that it may be difficult to properly remix a sample in a 1.0 cc syringe.

Sample on Ice

Fill the cartridge before icing the sample for transport. Icing will increase the potassium and will affect oxygen levels in samples collected in plastic syringes.

ARTERIAL PUNCTURE - COAGULATION TESTS

Blood Flow

Collection technique resulting in good blood flow must be used. Inadequate blood flow may produce erroneous results.

Plastic

The sample for testing should be drawn into a **plastic** collection device (syringe or blood collection tube) containing **no anticoagulant**.

Samples collected into glass tubes or syringes, or in tubes containing anticoagulants, cannot be used with the i-STAT coagulation cartridges.

Note: CLSI guidelines recommend the sample for coagulation testing be the second or third tube drawn when using a blood collection system (use a discard tube if this is the only sample being drawn) or be taken from the second syringe if a double syringe technique is used for drawing blood.

Time to Test

The sample must be immediately dispensed into the sample well of the cartridge and the cartridge must be inserted immediately into an analyzer.

Repeat Test

If a repeat measurement is needed, a fresh sample must be obtained.

ARTERIAL PUNCTURE - GLUCOSE TEST STRIPS (i-STAT®1 ANALYZER)

Anticoagulant

Use only fresh whole blood samples. Clear the arterial line before drawing a blood sample into a syringe that contains sodium heparin, lithium heaparin or EDTA.

Time to Test

Mix the syringe several times immediately before applying the sample to the target area of the test strip. Allow a drop of blood to form at the tip of the syringe. Cover the entire target area of the test strip with the blood sample. The syringe can briefly touch the test strip without affecting results. Use the sample within 30 minutes of collection.

INDWELLING LINE

Blood Gas, Electrolyte, Chemistry

Back flush line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.

Coagualtion Cartridges

If blood **must** be drawn from an indwelling line, possible heparin contamination should be considered. The line should be flushed with 5mL of saline and the first 5mL of blood or six dead space volumes of the catheter should be discarded.

SKIN PUNCTURE

Device

Use a puncture device that provides free-flowing blood. Inadequate blood flow may produce erroneous results.

Blood Gas Analysis

There are conflicting reports in the literature regarding the validity of PO_2 analysis performed on arterialized skin puncture specimens compared to arterial PO_2. The process of capillary collection may change PO_2, PCO_2, and the calculated sO_2. Arterial specimens are preferred for blood gas analysis.

Hemolysis

Avoid hemolysis (bursting of red cells) due to vigorous massaging or "milking."

Hemolysis will cause an increase in potassium results and a decrease in calcium results.

To increase blood flow, massage a finger gently from about three inches from the tip to the fleshy portion of the tip.

Avoid hemolysis by allowing residual alcohol to dry over the puncture site.

Tissue Fluid

For tests other than PT/INR cartridges, wipe away the first drop of blood as it may contain excess tissue fluid, which can increase potassium results, and decrease the other test results. (If only testing glucose by the strip method, it is not necessary to wipe away the first drop.)

Air

Avoid drawing air into the capillary tube.

Anticoagulant

Most heparinized capillary tubes are not suitable for electrolyte measurements, especially ionized calcium, due to the high concentration of heparin (50 U/mL or more). Use balanced heparin tubes or plain tubes.

If the sample is to be tested on a glucose test strip, the sample can be applied directly to the target area of the test strip or a capillary tube coated with sodium heparin, lithium heparin, or EDTA can be used to apply the sample to the test strip.

Time to Test

Test samples collected in capillary tubes immediately to avoid clotting (especially in neonates whose blood may clot more quickly).

Warming Area

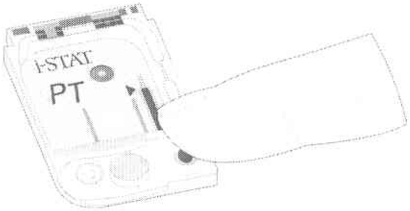
Blood flow can be stimulated by warming the puncture site. Follow the facility's policy and procedure for warming (arterializing) an infant's heel or other skin puncture area.

ACT, cTnI, CK-MB, and BNP Cartridges

Skin puncture samples are not recommended for ACT, cTnI, CK-MB, and BNP measurements.

PT/INR Cartridges

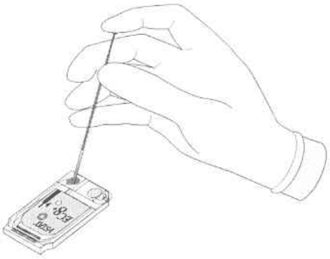
i-STAT PT/INR cartridges should be filled directly from the puncture site by allowing blood to flow from the site into the cartridge - no transfer device should be used.



SAMPLE TRANSFER DEVICES

Dispensers

A dispenser can be used to avoid the use of needles when transferring a blood sample from an blood collection tube.



Do not use dispensers that would introduce air into the sample when ionized calcium, pH, or PCO_2 are being measured.

For coagulation testing the dispenser **must be plastic** and must **not contain anticoagulant**.

Capillary Tube

While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred.

Capillary tubes can be used to transfer sample from a tube to a cartridge. For coagulation testing, the capillary tube **must be plastic** and must **not contain anticoagulant**.

Syringe

A 1cc syringe (such as a tuberculin) and needle (no smaller than 20 gauge) can be used to withdraw a sample from an blood collection tube.

Take care not to draw air with the sample when ionized calcium, pH, PCO_2, or TCO_2 are being measured.

For coagulation testing, the syringe **must be plastic** and must **not contain anticoagulant**.

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PROCEDURE FOR HANDLING CARTRIDGES 11

PREPARATION FOR TESTING

Select the Cartridge Select the appropriate cartridge for the test or tests required. While the cartridge is not fragile, it should be handled as follows to avoid difficulty in filling and Quality Check failures.

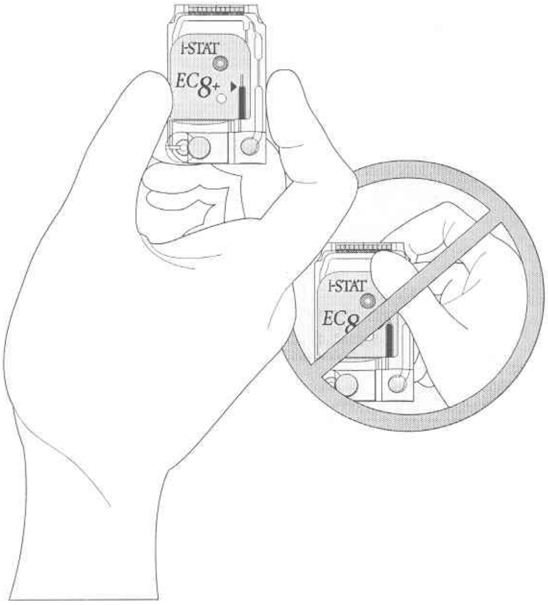
Room Temperature A cartridge should not be removed from its protective pouch until it is at room temperature (18-30 °C or 64-86 °F). For best results, the cartridge and analyzer should be at the temperature of the room where they are to be used. Condensation on a cold cartridge may prevent proper contact with the analyzer. Allow a single cartridge to stand for 5 minutes and a box of cartridges for 1 hour at room temperature before use. Use a cartridge immediately after removing it from its protective pouch — prolonged exposure may cause a cartridge to fail a Quality Check. If the pouch has been punctured, the cartridge should not be used. Once cartridges have been brought to room temperature, they should not be returned to the refrigerator. Cartridges may be stored at room temperature for two weeks.

Contact Pads Do not contaminate the contact pads with fingerprints or talc from gloves as the analyzer may not be able to make proper contact with the cartridge.

Calibrant Pack Do not apply pressure to the central area of the label as the calibrant pack inside could burst prematurely.

Air Vent Do not block the air vent as the sample will not flow to the fill mark and the calibrant solution will not flow to the sensors.

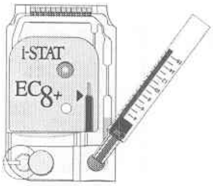
Contamination To avoid contaminating the analyzer do not use a cartridge on which blood or any other fluid has spilled. Avoid filling cartridges on surfaces that may cause the cartridge to pick up fibers, fluid or debris that may lodge in the analyzer.

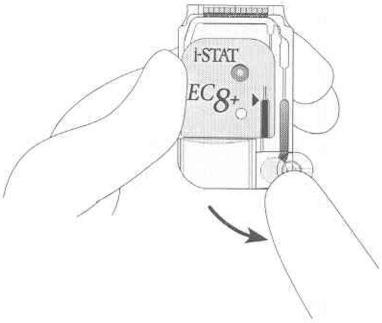


FILLING AND SEALING CARTRIDGE USING TRANSFER DEVICE

Procedure

STEP	ACTION
1	Place the cartridge on a flat surface or hold it in a horizontal position.
2	Direct the tip of the syringe, capillary tube or dispenser into the sample well.
3	Dispense sample slowly and steadily until it reaches the fill mark indicated on the cartridge label. Leave some sample in the sample well.
4	Fold the snap closure over the sample well.
5	Press the rounded end of the closure until it snaps into place.



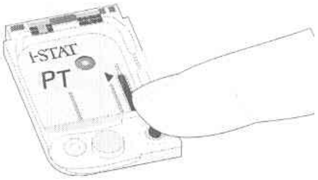


Caution

Do not hold cartridge between the fingers if using a syringe with needle to fill.

FILLING AND SEALING PT/INR (PROTHROMBIN TIME) CARTRIDGES USING DIRECT FINGERSTICK SAMPLING

STEP	ACTION
1.	Remove cartridge from foil pouch and place the cartridge on a flat surface.
2.	Prepare lancet device and set aside until needed.
3.	Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
4.	Prick the bottom side of the fingertip with the lancet device.
5.	Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.*
6.	Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7.	Apply sample until it reaches the fill mark indicated on the cartridge.



8. Fold the sample closure over the sample well.

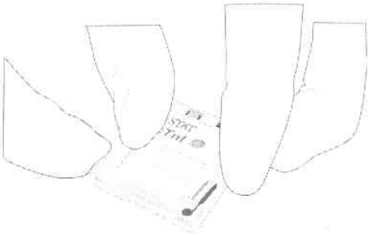
9. Press the rounded end of the closure until it snaps into place.

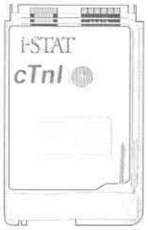
Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat vibration-free surface for testing.

FILLING AND CLOSING A cTnI CARTRIDGE USING TRANSFER DEVICE

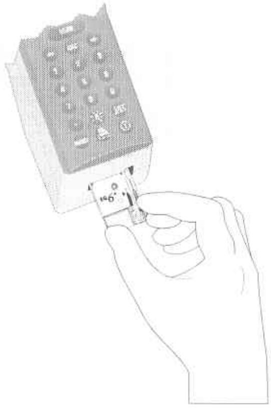
1. Following thorough mixing of the sample, direct the transfer device (either syringe tip or pipette tip) into the inlet port. Apply a single drop of sample to the inlet port. If the cartridge fill is incomplete as seen via the fill indicator on the cartridge label, apply a second small drop until the sample reaches the fill mark.
2. To close the cTnI Cartridge:
   a. first anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cTnI cartridge from its side edges away from the sample inlet.

   b. use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. *Note: When sliding the closure clip, the index finger of that same hand should not be placed directly across from the thumb, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not used at all.*





STEP	ACTION
Inserting Cartridge into Analyzer	
1	Align the cartridge with the contact pads facing up and toward the cartridge port.
2	Push the cartridge slowly and smoothly into the cartridge port until it clicks into place.
Removing Cartridge from Analyzer	
3	Do not attempt to remove the cartridge while the message "Cartridge Locked" remains on the screen.
4	When results are displayed, pull the cartridge straight out of the analyzer.
5.	Dispose of the cartridge in a container for biohazards, following local, state, and national regulatory guidelines.



INCORRECT PROCEDURE

Overview

The cartridge is designed to fill and seal correctly. However, the conditions described below may occur, especially during the training period. If the condition is not detected by the operator, the analyzer will detect the condition, halt the test cycle and display a cause message followed by the action message "USE ANOTHER CARTRIDGE."

Condition	Operator Action	Analyzer Display
Sample beyond fill mark.	If the sample flows only slightly beyond the fill mark, the cartridge can still be used. If the sample is close to or enters the air segment chamber, use another cartridge.	SAMPLE POSITIONED BEYOND FILL MARK
Sample not up to fill mark.	If the sample well fills but the sample does not reach the fill mark, ensure that the air vent (small hole on the underside of the cartridge) is not blocked. Tilt the cartridge slightly so that gravity aids the flow. When the sample starts to flow into the chamber, return the cartridge to the horizontal position. If the sample is considerably short of fill mark, the analyzer will detect the condition and halt the test cycle.	SAMPLE POSITIONED SHORT OF FILL MARK
Sample well empty.	If the sample reaches the fill mark, but the sample well is left completely empty, there may be insufficient sample for the test.	INSUFFICIENT SAMPLE
Air bubbles in sample.	If air bubbles are trapped in the sample chamber, discard the cartridge and fill another.	INSUFFICIENT SAMPLE
Sample well overfilled.	If the sample well is so full that sample is seen above the sample well after the sample chamber is filled, do not wipe or absorb the excess with a gauze or tissue but draw the excess back into the syringe or a capillary tube. If the sample spreads over the outside of the sample well, an airtight seal may not form when the cartridge is closed. In this case the analyzer may not be able to move or position the sample over the sensors.	UNABLE TO POSITION SAMPLE
Sample clotted.	If the sample clots in the sample well the analyzer will not be able to move or position the sample over the sensors.	UNABLE TO POSITION SAMPLE
Cartridge contaminated.	If sample spills onto the cartridge or if the cartridge has collected debris, discard the cartridge. Inserting a contaminated cartridge into the analyzer will cause debris to build up on the pins that contact the cartridge pads which will cause a cartridge or analyzer Quality Check code.	CARTRIDGE ERROR or ANALYZER ERROR
Sample pushed beyond fill mark.	Avoid applying excess pressure on the closure directly over the sample well as doing so may push the sample beyond the fill mark.	SAMPLE POSITIONED BEYOND FILL MARK
Cartridge sealed before sample reaches fill mark.	Closing the cartridge before the sample chamber has filled will stop the flow of the sample to the fill mark.	SAMPLE POSITIONED SHORT OF FILL MARK
Cartridge not sealed before inserted into analyzer.	Failure to close the cartridge before inserting it into the analyzer will prevent sample movement and can cause the sample to flow backward and out of the sample well.	UNABLE TO POSITION SAMPLE.

i-STAT®1
System Manual

Abbott
Point of Care

Rev. Date: 08/14/06

Art: 714336-00E

Patents

CA 1,281,072; CA 1,303,175; CA 1,330,888; CA 2,002,848; CA 2,087,720; CA 2,087,966; CA 2,175,228; CA 2,193,000; CA 2,194,795; CA 2,221,178; EP 0408575; EP 0412119; EP 0434742; EP 0442969; EP 0505169; EP 0540691; EP 0543916; JP 2113412; JP 2521826; JP 2833809; JP 2948321; JP 3093274; JP 3105919; JP 3105922; JP 3137612; JP 3269553; JP 3392871; US 4,864,229; US 4,933,048; US 4,954,087; US 5,008,616; US 5,096,669; US 5,112,455; US 5,121,050; US 5,124,661; US 5,200,051; US 5,447,440; US 5,466,575; US 5,514,253; US 5,554,339; US 5,605,664; US 5,609,824; US 5,614,416; US 5,628,961; US 5,789,253; US 5,821,399; US 5,837,446; US 6,030,827; US 6,379,883; US 6,438,498; US 6,750,053; US D332,833; US D337,164

Symbol Technologies Corporation is the owner of US Patent Nos. 4,758,717; 5,130,520; 5,262,628; 5,396,055; 5,532,469.

Trademarks

i-STAT is a registered trademark of Abbott Laboratories. MediSense is a registered trademark of Abbott Laboratories. Precision and PCx are trademarks of Abbott Laboratories. Windows is a registered trademark of Microsoft Corporation.

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PROCEDURE FOR CARTRIDGE TESTING 12

Caution

The following cautions should be taken to prevent damage to the analyzer and to ensure the safety of the operator and the integrity of results.

- Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent eye damage.
- Do not attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the analyzer. The message "Cartridge Locked" will remain on the screen until the analyzer unlocks the cartridge.
- The analyzer may be contaminated with blood from prior use. Whenever handling the analyzer, cartridges, and peripherals exercise universal precautions to protect yourself from blood-borne pathogens. Universal precautions are those procedures and practices, such as the wearing of gloves, designed to protect personnel from blood-borne pathogens as well as pathogens from other body substances. These precautions are based on the assumption that blood, body fluids or tissue can contain infectious agents and, therefore, should be treated as a biohazard. For more detailed information, please refer to either the CDC/NIH manual, "Biosafety in Microbiological and Biomedical Laboratories", Fourth Edition, 1999, or the WHO "Laboratory Biosafety Manual", Second Edition, 2003.

  To protect from nosocomial infections, decontaminate analyzers periodically and whenever blood is spilled or transferred to an analyzer. See under "Cleaning the Analyzer and Downloader" in section 17 of this manual.
- A falling analyzer may cause injury. Always place the analyzer and peripherals on a stable surface or in a location where it will not cause injury if dropped.
- The analyzer may be rendered inoperative by damage due to mishandling, such as dropping, by exhausting the batteries or by other causes. Clinical settings that demand fail-safe testing should reduce this risk by having a backup analyzer or test source available.
- The analyzer should not be used in environmental conditions that exceed the operating temperature and humidity specifications. An analyzer that has been exposed to extreme environmental conditions must be allowed to come to equilibrium with the operating environment prior to use. Note: the analyzer will display the message "Temperature Out of Range" until it has reached its operating temperature.
- The analyzer and its peripherals are not listed by any authority with respect to suitability for use in oxygen enriched atmospheres.
- Proper procedure must be used to ensure correct manual entry of patient ID, operator ID, sample type and other data that may affect the clinician's interpretation of results.

PERFORMING PATIENT ANALYSIS WITH CARTRIDGE – INFORMATION FIRST DISABLED

Procedure

This procedure is used when the analyzer is customized to allow the operator to enter Operator and Patient IDs after a cartridge has been inserted into the analyzer. To run immunoassay cartridges in this mode, you must have "Cartridge Barcode Required" enabled in the analyzer customization.

Display	Action	Analyzer Response / Comments
The display may be blank or a result may be displayed.	Insert filled cartridge into analyzer's cartridge port.	Test cycle initiated. Analyzer may display a startup warning message. If at any point during the test cycle a Quality Check fails, the test cycle will halt and a message will be displayed indicating the condition and corrective action.
Scan or Enter Cartridge Lot Number (if Barcode Required enabled)	Press **Scan** to scan cartridge lot number or manually enter the lot number and press **Enter**	
Enter or Scan Operator ID Cartridge Locked	Press **Scan** to scan the Operator ID or manually enter using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Patient ID Cartridge Locked	Press **Scan** to scan the Patient ID or manually enter using the keypad and press **Enter**. **Note:** If an External Simulator was inserted instead of a cartridge, the analyzer will prompt for the Patient ID and then for the Simulator ID.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated. If enabled, the most recent patient ID can be recalled by pressing the → key.

PERFORMING PATIENT ANALYSIS WITH CARTRIDGE – INFORMATION FIRST DISABLED (CONTINUED)

Display	Action	Analyzer Response / Comments
Scan or Enter Cartridge Lot Number *(if Cartridge Lot enabled)*	Press **Scan** to scan Cartridge Lot Number or manually enter the Lot Number and press **Enter**.	
i-STAT (Cartridge panel number) Time to Results →Page Cartridge Locked	If the Test Selection page is displayed, use the number keys to select tests to be reported. (Press a number key again to deselect a test.) If the Chart page is automatically displayed, enter the required information. If not, press the → key to go to the Chart page.	Displays screens enabled in the customization profile for the analyzer.
ID Scan or Enter Data Sample Type _ Field 1 --------- Field 2 --------- Field 3 --------- Pt Temp ----- FI02 --- CPB NO 1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR → Page Cartridge Locked	Enter information on Chart page if desired. Use the **Enter** key to move from field to field. For CPB the choices are 1 – YES and 2 – NO. Default is NO. Use the → key to return to the results page.	Information entered on the Chart and Test Selection pages can be changed up until: • the next test is initiated. • results are transmitted. • the **Menu** key is used to backup to the Test Menu screen. • A test option is selected. **Note**: CPB is included on the screen only when the cartridge includes a sensor for hematocrit.
Results or Results Ready message	If not on results page, press the → key to return to the results page.	Analyzer unlocks the cartridge and is ready for another test. Tests disabled in customization will not be displayed.
Optional prompt above results	If Comment Code is enabled, scan or manually enter a comment code.	The analyzer can be customized to request a comment code for results that are inside action ranges and for results that exceed action ranges.
Results page 1-Test Options	Test Options Patient 1 - Next Patient 2 - Same Patient 3 - History	

PERFORMING PATIENT ANALYSIS WITH CARTRIDGE – INFORMATION FIRST ENABLED

Procedure

This procedure is followed when the analyzer has been customized to require the operator to enter Operator and Patient IDs before inserting a cartridge. If the operator inserts a cartridge before entering Operator and Patient IDs, the message "Remove Cartridge" will be displayed. To run immunoassay cartridges in this mode, you must have "Cartridge Lot Number Required" enabled in the analyzer's customization profile.

Display	Action	Analyzer Response / Comments
Blank or active.	Press the **On/Off** key to turn on the analyzer. If the analyzer is already on, press the **Menu** key to get to the Test Menu, or turn the analyzer off and back on again.	Logo briefly displayed followed by Test Menu. If a test strip or cartridge is inserted in analyzer, the analyzer will prompt to remove. Analyzer may display a startup warning or Quality Check message.
Test Menu 1 – Last Result 2 – i-STAT Cartridge 3 – PCx Glucose Strip	Press **2** to select i-STAT Cartridge.	If the glucose strip function is disabled, option 3 will not be displayed.
Enter or Scan Operator ID	Press **Scan** to scan the Operator ID or manually enter using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Patient ID	Press **Scan** to scan the Patient ID or manually enter using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated. If enabled, the most recent patient ID can be recalled by pressing the → key.

PERFORMING PATIENT ANALYSIS WITH CARTRIDGE – INFORMATION FIRST ENABLED (CONITNUED)

Display	Action	Analyzer Response / Comments
Scan or Enter Cartridge Lot Number (if enabled)	Press **Scan** to enter the Lot Number or manually enter the Lot Number and press **Enter**.	Scanning the cartridge lot number is required for cTnI testing.
INSERT CARTRIDGE	Insert filled cartridge into the analyzer's cartridge port.	The analyzer will display the "INSERT CARTRIDGE" message for 15 minutes to allow for blood collection before turning off.
Identifying Cartridge please wait... i-STAT (Cartridge panel number) Time to Results → Page Cartridge Locked *Screens may be displayed automatically*	If Test Selection is displayed, use the number keys to select tests to be run. (Press a number key again to deselect a test.) If Chart page is displayed, scan or manually enter the required information. If not, press the → key to go to the Chart page.	Displays screens enabled in the customization profile for the analyzer. If at any point during the test cycle a Quality Check fails, the test cycle will halt and a message will be displayed indicating the condition and corrective action.
ID Scan or Enter Data Sample Type _ Field 1 --------- Field 2 --------- Field 3 --------- Pt Temp ----- FIO2 --- CPB NO 1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR → Page Cartridge Locked	Enter information on Chart page if desired. Use the **Enter** key to move from field to field. For CPB the choices are 1 – YES and 2 – NO. Default is NO. Use the → key to return to the results page.	Information entered on the Chart and Test Selection pages can be changed up until: • the next test is initiated. • results are transmitted. • the **Menu** key is used to backup to the Test Menu screen. • A test option is selected. **Note**: CPB is included on the screen only when the cartridge includes a sensor for hematocrit.

PERFORMING PATIENT ANALYSIS WITH CARTRIDGE – INFORMATION FIRST ENABLED (CONITNUED)

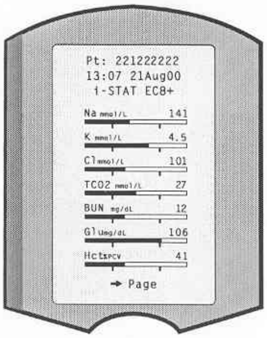
Display	Action	Analyzer Response / Comments
Results or Results Ready message	If not on results page, press the→ key to return to the results page.	Analyzer unlocks the cartridge and is ready for another test.
Optional prompt above results	If Comment Code is enabled, scan or manually enter a comment code.	The analyzer can be customized to request a comment code for results that are inside action ranges and for results that exceed action ranges.
Results page 1-Test Options	Test Options Patient 1 - Next Patient 2 - Same Patient 3 - History	

INTERPRETATION OF DISPLAYED RESULTS

Results Display

Test results are displayed with numerical concentration values in the units selected for the Customization profile. For patient test results, bar graphs depicting the values in relation to reference ranges are also displayed. Reference ranges are marked on the bars by tic marks. When all test values are within their reference ranges, the tic marks will be centrally aligned. The bar graphs can be used as a visual cue for distinguishing between "normal" and "abnormal" results. Blood gas, coagulation, and cTnI results are not displayed with bar graphs and reference ranges.

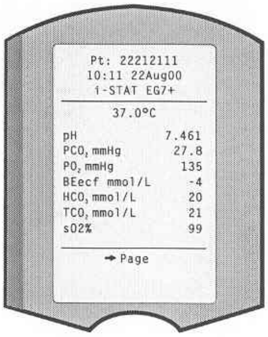
If a value exceeds the reference range, the bar graph may be rescaled to show the reference range and value in relation to the measurement range.



```
Pt: 221222222
13:07 21Aug00
i-STAT EC8+
Na mmol/L      141
K mmol/L       4.5
Cl mmol/L      101
TCO2 mmol/L     27
BUN mg/dL       12
Glu mg/dL      106
Hct %PCV        41
→ Page
```

Reportable Ranges

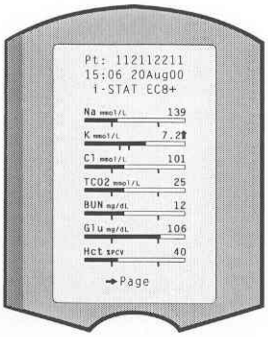
The reportable range (sometimes referred to as the linear range) is the concentration range over which test results are valid. Reportable ranges programmed into the analyzer can are listed in the Cartridge and Test Information section.



```
Pt: 22212111
10:11 22Aug00
i-STAT EG7+
37.0°C
pH               7.461
PCO2 mmHg         27.8
PO2 mmHg           135
BEecf mmol/L        -4
HCO3 mmol/L         20
TCO2 mmol/L         21
sO2%                99
→ Page
```

Reference Ranges

Reference ranges (sometimes referred to as normal ranges) in the default Customization profile are derived from the literature and are listed in the Cartridge and Test Information section as well as in the Customization option on the analyzer. Variables such as sex, age, heritage and other demographic factors of a population may cause a shift in these ranges. Therefore, it is usually recommended that each facility determine its own reference ranges. Reference ranges can be changed using the Customization function on the Central Data Station.



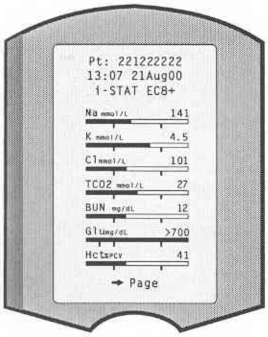
```
Pt: 112112211
15:06 20Aug00
i-STAT EC8+
Na mmol/L      139
K mmol/L      7.2↑
Cl mmol/L      101
TCO2 mmol/L     25
BUN mg/dL       12
Glu mg/dL      106
Hct %PCV        40
→ Page
```

Action Ranges

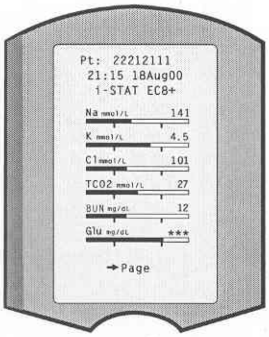
Action ranges (sometimes referred to as critical values) indicate results that require immediate attention. When a test result falls outside the action range it is flagged as either above the high action range ↑ or below the low action range ↓. Action ranges are programmed into the analyzer using the Customization function on the Central Data Station and can be viewed on the analyzer under the Customization option.

Flags

When the analyzer detects an out-of-range result or an uncharacteristic sensor signal, the condition is indicated by a flag. See table below for flags and symbols used with results. Note: The reportable range flags do not apply when testing is performed under Quality Tests Option 3 – **Cal Ver**. Action flags do not apply to Option 1 – **Control** or Option 3 – **Cal Ver**.



```
Pt: 221222222
13:07 21Aug00
i-STAT EC8+
Na mmol/L       141
K mmol/L        4.5
Cl mmol/L       101
TCO2 mmol/L      27
BUN mg/dL        12
Glu mg/dL      >700
Hct %PCV         41
→ Page
```



```
Pt: 22212111
21:15 18Aug00
i-STAT EC8+
Na mmol/L       141
K mmol/L        4.5
Cl mmol/L       101
TCO2 mmol/L      27
BUN mg/dL        12
Glu mg/dL       ***
→ Page
```

Display	Action	Analyzer Response / Comments
>	The result falls above the reportable range of the test.	If an ACT result is displayed as >1000, the result should be reported as "greater than 1000 seconds."
<	The result falls below the low end of the reportable range of the test.	If a pH result is displayed as <6.5, the result should be reported as "less than 6.5."
< >	The result is dependent on another test that has been flagged. The < > flag will also be displayed for TCO2, pH, *P*CO2, HCO3, anion gap, base excess and sO2 if the TCO2 is outside the reportable range. Because the values outside the reportable range of TCO2 are essentially non-physiological, the TCO2 range check is used as an additional quality check on the validity of the underlying pH and *P*CO2 results.	If a sodium result is displayed as >180, the calculations for potassium, chloride, BUN/Urea and hematocrit, which depend upon the sodium measurement, will be flagged < >.
↑	The result is above the high action range.	If the action ranges for potassium are 3.2 and 5.5, a result of 6.0 will be displayed as 6.0 ↑.
↓	The result is below the low action range.	If the action ranges for potassium are 3.2 and 5.5, a result of 3.0 will be displayed as 3.0 ↓.
***	The signals from a particular sensor are uncharacteristic. Uncharacteristic signals can be caused by a compromised sensor or by an interferent in the sample. This flag also appears for any test dependent on another test which is flagged with stars.	The sample should be retested using another cartridge. If the stars reappear, refer to the troubleshooting paragraph in this section of the manual.

Warning Message

If testing is disabled due to warning message, the condition must be corrected and the analyzer must be turned off and back on again before testing is enabled.

Message and Quality Check Code

See Troubleshooting section

***** Instead of Results**

Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Since the sensor check is part of the i-STAT quality system, an occassional result will be flagged due to a bad sensor. Other causes of this flag are improperly stored cartridges or an interfering substance in the patients sample, either extrinsic, such as the wrong anticoagulant, or intrinsic such as medication. Also, aged samples may contain products of metabolism that can interfere with the tests.

- Check the supply of cartridges in use with a control solution.
- If the control is in range, draw a fresh sample from the patient and retest.
- If the stars appear in place of results again, there may be an interfering substance. Refer to the Cartridge and Test Information section for a list of interfering substances. Test the sample using another method.
- If the control is out-of-range or if stars are displayed in place of results, there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and contact your support representative. (Refer to Support Services information in the Troubleshooting section.)

Unexpected Results

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information sheets for the test in question. Test by another method to verify the result. If the controls are out of range there may be a problem with the cartridge lot number. Use another lot number or repeat the test using another method, and contact your support representative. (Refer to Support Services information in the Troubleshooting section.)

PROCEDURES FOR GLUCOSE TEST STRIP TESTING 13

Operating Guidelines for All Samples

Follow the recommended guidelines to obtain the most accurate results.

- Use the test strips before their expiration date.
- Do not use test strips that are wet, bent, scratched or damaged.
- Use the test strip immediately after opening its foil packet.
- Do not scan a packet's barcode and use a test strip from another packet. This may cause incorrect assay results to be generated.
- Cover the entire target area of the test strip with the blood sample. The test results will not be affected if the target area has been briefly touched with the patient's finger, a syringe, a capillary tube or pipette.
- If the test fails to start, apply a second drop of blood to the target area within 30 seconds. If the test fails to start after the second drop is applied, or if more than 30 seconds have passed, discard the used test strip and repeat the test.
- After the blood is applied to the test strip and the test starts, do not touch the strip.
- Use a new test strip when repeating a patient test.
- Refer to the package insert in the test strip box for specific directions on storage and use of the test strips.
- Store analyzers in use near the testing location or in an area close to the same temperature as the testing area. Do not store analyzers near equipment that gives off heat or in the direct sunlight. If an analyzer is moved to a testing area that is slighly cooler or warmer (5 °C or 9 °F) than the previous testing or storage area, allow 30 minutes for the analyzer to equilibrate to the temperature of the new testing area before using the analyzer. If the temperature difference is substantial allow 90 minutes for equilibration.
- i-STAT 1 Analyzers may require a modification to the glucose strip port in order to be compatible with Precision PCx Plus Glucose Test Strips. This modification can be identified by noting the analyzer serial number and by inspecting the glucose strip port.

Analyzer Serial Number	Blue Strip Port Spacer Present?	Strip Port Modification Needed?
$\geq$ 317900	No	No
< 317900	Yes	No
< 317900	No	Yes. Contact i-STAT Technical Support at 1-800-366-8020, option 1 for information on modifying the port. The modification is easily self-installed.

PERFORMING PATIENT GLUCOSE ASSAY WITH TEST STRIP

Procedure If the analyzer displays a message not indicated in this procedure, refer to the Troubleshooting section of this manual.

Caution Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent eye damage.

Display	Action	Analyzer Response
Blank or active.	Press the **On/Off** key to turn the analyzer on. If the analyzer is on, press the **Menu** key to return to the Test Menu or turn the analyzer off and back on.	Logo briefly displayed followed by Test Menu.
Test Menu 1 – Last Results 2 – i-STAT Cartridge 3 – PCx Glucose Strip	Press **3** to select PCx Glucose Strip.	REMOVE STRIP will be displayed if a strip is inserted before the analyzer displays INSERT STRIP.
Precision PCx Blood Glucose Strip 1 – Patient 2 - Control	Press **1** to select Patient.	Possible message: "Control Required Patient Testing Disabled"
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Patient ID	Press **Scan** to scan the Patient ID, or manually enter the Patient ID using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated. If enabled, the most recent patient ID can be recalled by pressing the → key.
Scan or Enter Strip Lot Number	Press **Scan** to scan the Strip Lot Number, or manually enter the Strip Lot Number using the keypad and press **Enter**. (see Note below)	Possible messages: "Lot Expired, " "Invalid Number, " "Invalid Length, " "Strip Lot xxx Is Not in List"

PERFORMING PATIENT GLUCOSE ASSAY WITH TEST STRIP (CONTINUED)

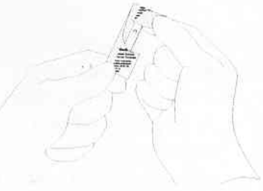


figure 13.1

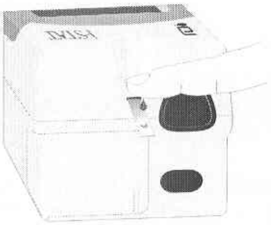


figure 13.2

Display	Action	Analyzer Response
Select Sample Type 1 – Arterial or Capillary 2 - Venous	Press **1** or **2** to select the correct sample type.	This prompt will not be displayed if the analyzer has been customized for one sample type only.
INSERT STRIP	Open the foil test strip packet at the notch and tear up or down to remove the test strip. (see figure 13.1) With the contact bars facing up, insert the test strip into the test strip port until it stops.	The analyzer will display the "INSERT STRIP" message for 2 minutes. If the strip is not inserted, the analyzer will turn off.
Apply Arterial/Capillary Sample or Apply Venous Sample	Apply a drop of blood directly from the patient's finger or a syringe to the target area on the test strip. (see figure 13.2)	The analyzer beeps when the sample is accepted. The tests starts automatically as the sample is accepted.
Precision PCx Blood Glucose Strip Time to Results → Page	Press the → key to enter Chart page information if desired. Press the → key again to return to the result page.	The analyzer counts down 20 seconds, then displays the test result. If the → key is pressed, the Chart page will be displayed. The sample type will be displayed along with 3 free fields in which comments of 9 characters each can be entered. The analyzer may be customized to present the Chart page automatically.
Result	Remove the test strip from the analyzer when finished testing.	If Action Ranges are enabled, and the result is outside the range, an up (high) or down (low) arrow will be displayed with the result. If Comment Code is enabled, the analyzer will request the operator to Scan or Enter Comment Code. Up to 3 characters can be entered.
Result 1 – Test Options	Test Options Patient 1 - Next Patient 2 - Same Patient 3 - History	

Note: If valid strip lot numbers are programmed into the analyzer, only the first six digits of the strip lot number need be entered via the keypad. The analyzer will fill in the remaining eight digits of the 14 digit lot number. If the strip lot number is not recognized the analyzer will prompt for the remaining 8 digits.

CAUTION

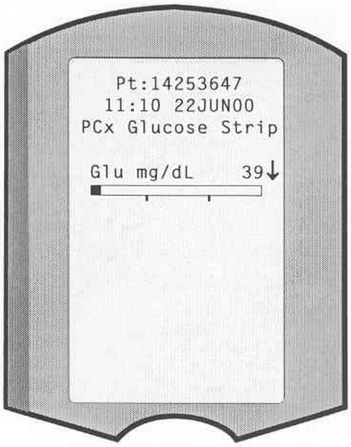
The following cautions should be taken to prevent damage to the analyzer and to ensure the safety of the operator and the integrity of results.

- Never look into the barcode scanner beam or point it toward anyone's eyes. The beam could cause permanent damage in the eye.
- The analyzer may be contaminated with blood from prior use. Whenever handling the analyzer, exercise standard precautions to protect yourself from blood-borne pathogens. Standard precautions are those procedures and practices, such as the wearing of gloves, designed to protect personnel from blood-borne pathogens as well as pathogens from other body substances. These precautions are based on the assumption that blood, body fluids or tissue can contain infectious agents and, therefore, should be treated as a biohazard.
- A falling analyzer may cause injury. Always place the analyzer on a stable surface or in a location where it will not cause injury if dropped.
- The analyzer may be rendered inoperative by damage due to mishandling, such as dropping, by exhausting the batteries, or by other causes. Clinical settings that demand fail-safe testing should reduce this risk by having a backup analyzer or test source available.
- The analyzer should not be used in environmental conditions that exceed the operating temperature and humidity specifications. An analyzer that has been exposed to extreme environmental conditions must be allowed to come to equilibrium with the operating environment prior to use. Note: the analyzer will display the message "Temperature Out of Range" until it has reached its operating temperature.
- Proper procedure must be used to ensure correct manual entry of patient ID, operator ID, sample type and other data that may affect the clinician's interpretation of results.
- Follow test strip QC procedures and frequency described in the Quality Control section of this manual.

INTERPRETATION OF DISPLAYED RESULTS

Results Display

The glucose value is displayed in the units selected for the analyzer's customization profile. The result is also displayed as a bar graph with the Reference Range depicted as tic marks under the graph.



```
Pt:14253647
11:10 22JUN00
PCx Glucose Strip

Glu mg/dL      39↓
```

Reportable Range and < and > Flags

The reportable range (linear range) is the concentration range over which test results are valid. When a result falls below the reportable range it is displayed as < 20 mg/dL or <1.1 mmol/L. For the Precision PCx blood glucose strip, when a result falls above the reportable range it is displayed as >600 mg/dL or >33.3 mmol/L. The PCx Plus strip will display >500mg/dL or > 27.8 mmol/L

Reference Range

The reference range (normal range) pre-programmed into the analyzer is derived from the literature and can be changed using the Customization function on the Central Data Station.

Action Range and ↓↑ Flags

Action ranges can be programmed into the analyzer using the Customization function on the Central Data Station. Results falling below the lower action range will be displayed with ↓ and results falling above the upper action range will be displayed with ↑.

TROUBLESHOOTING

Possible Reasons for Higher than Expected Results

- Hematocrit < 20 %PCV or 0.20.
- Serum or plasma samples used instead of whole blood.
- Room (ambient) temperature > 104 °F or 40 °C.
- Relative humidity >90%
- Venous blood tested in capillary or arterial mode.

Possible Reasons for Lower than Expected Results

- Hematocrit >70%PCV or 0.70.
- Room temperature <59 °F or 15 °C.
- Capillary or arterial blood tested in venous mode.
- Relative humidity <10%.
- Acetaminophen >100 µg/mL.
- Hyperglycemic-hyperosmolar state (with or without ketosis).
- Severe dehydration, hypotension or shock.
- Water or alcohol remaining on the puncture site.
- Venous or arterial whole blood sample not tested within 30 minutes after collection.

Repeat Testing

When the > flag occurs, or if the result is outside the action ranges designated for the location, the sample must be tested by another method, such as an i-STAT glucose cartridge, in order to obtain a result.

QUALITY CONTROL 14

Overview

This section describes the steps to be taken to verify the performance of the analyzer, cartridges and test strips. The rationale for the i-STAT catridge and analyzer quality regimen is described in the Theory section of this manual.

Customization

The quality control behavior of the analyzer can be customized via the Central Data Station or analyzer Customization Change function to:

- turn the external Electronic Simulator reminder on or off.
- prompt the operator to use the external Electronic Simulator at scheduled intervals.
- turn the internal Electronic Simulator on or off , and select the simulator test cycle intervals.
- disable further cartridge testing when the internal Electronic Simulator test fails.
- include the Normal/Mid Glucose Control in the control regimen for test strip testing.
- prompt the operator to test strip controls in intervals of hours, at daily pre-determined times, or by number of patient tests.

See the Customization section for default values.

Data Retention

Quality control data is transmitted to the Central Data Station. If a Central Data Station is not being used, the charts at the end if this section can be used to record liquid and electronic control results.

QUALITY CONTROL FOR i-STAT CARTRIDGES AND THE ANALYZER'S CARTRIDGE TEST CYCLE

Verify Newly Received Cartridges

1. Verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included in the shipping container.
2. From each lot in each shipment of cartridges, analyze multiple levels of i-STAT controls (and MeterTrax™ or RNA® Medical controls if testing for hematocrit) using any verified analyzer.

Verify Performance of Analyzers Daily

Verify the performance of each analyzer on site using the Electronic Simulator (external or internal) once a day on the days the analyzers are in use. Note that regulatory or accreditation requirements may dictate more frequent intervals.

Check Refrigerator Storage Daily

Verify that the cartridges stored in the refrigerator are within the expiration date printed on the boxes.

Verify that the storage refrigerator did not exceed the temperature limits of 2 to 8 °C (35 to 46 °F). If storage conditions are in doubt, use controls to verify that the cartridges are performing properly. This is especially important if freezing conditions are suspected at the back of the refrigerator.

Check Room Temperature Storage Daily

Verify that the cartridges stored at room temperature are within the expiration date and that the cartridges have been out of the refrigerator less than two weeks. If the temperature at which the cartridges are stored is in doubt, use controls to verify that the cartridges are performing properly.

Check Thermal Control System Twice a Year

i-STAT analyzers contain a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature ± 0.15°C.

A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. Therefore, i-STAT recommends that the thermal probe check be verified twice a year.

Check the Analyzer Ambient Temperature Reading Once a Year

The analyzer uses ambient temperature measurements to ensure that the temperature is within the operating range and in the extrapolation of ambient temperature measurement results for ionized calcium, pH and PCO_2 to 37 °C results.

CONTROLS FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES (EXCEPT CHEM8+ CARTRIDGES)

Control Solutions

Aqueous assayed control fluids are available for verifying the integrity of newly received cartridges. i-STAT Level 1, 2 and 3 Controls are formulated at three clinically relevant levels with known pH and with known concentrations of:

- Sodium
- Potassium
- Chloride
- Ionized Calcium
- PCO_2
- PO_2
- Glucose
- Lactate
- BUN/Urea
- Creatinine

Each level of control is packaged in a box of 10 ampules with a sheet with target values and acceptable ranges. Control solutions are contained in 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients

Analyte	Calibration Verification Level 1	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	108	127	141	169	187
K (mmol/L)	2.3	3.1	4.0	6.8	8.5
Cl (mmol/L)	71	85	100	122	133
Glu (mmol/L)	1.8	2.5	7.3	17	35
Urea (mmol/L)	44.6	18	4	2.7	1.8
iCa (mmol/L)	2.5	1.6	1.3	0.8	0.2
Lac (mmol/L)	19.5	8.4	2.3	1	0.6
Crea (µmol/L)	1486	386	155	46	17
PO_2 (mmHg)	43	61	100	140	400
PCO_2 (mmHg)	95	66	30	22	18
H^+ (pH)	6.81	7.15	7.41	7.60	7.95

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and analyzer should be at the same temperature.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested.

Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for ionized calcium, pH, PCO_2, or PO_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.

Before Use

i-STAT control solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.

Procedure

STEP	ACTION
1	Access the i-STAT Cartridge Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results. Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringe with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included with each box of control ampules.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the target value table matches the software revision in the analyzer.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls.

Target Values are specific to the i-STAT System. Results obtained from these aqueous controls with other methods may differ due to sample matrix effects.

Correction of PO_2 at Extreme Altitude

The partial pressure of oxygen in a solution will change as it equilibrates to the surrounding ambient pressure. The rate of change is faster in aqueous solutions than in whole blood due to the absence of red blood cells containing hemoglobin which binds oxygen molecules. This is of practical significance when testing aqueous solutions on blood gas analyzers as there will be a detectable shift in the partial pressure of oxygen in the sample as it equilibrates to the pressure in the flowpath of the analyzer.

The ranges for i-STAT aqueous control solutions are established for the degree of oxygen equilibration which occurs in the cartridges at or near sea level. PO_2 results for aqueous solutions, including i-STAT controls and Calibration Verification Set and proficiency (external quality control) samples, can be corrected for higher altitude environments using the following equations. Observed PO_2 values should be corrected before comparing them to the values in the value assignment sheet included with each box of i-STAT controls.

Equations:

For PO_2 values below 150 mmHg:

PO_2 corrected = PO_2 observed + (0.067 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 15 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

For PO_2 value above 150 mmHg:

PO_2 corrected = PO_2 observed + (0.029 x (760 – BP))

Where BP is the barometric pressure reading from the Analyzer Status screen.

(Approximate change: For every decrease of 35 mmHg in pressure from 760 mmHg, add 1 mmHg to observed value.)

CONTROLS FOR CHEM8+ CARTRIDGES

Control Solutions

Aqueous assayed control fluids are available for verifying the integrity of newly received CHEM8+ cartridges. i-STAT CHEM8+ Level 1, 2 and 3 Controls are formulated at three clinically relevant levels with known concentrations of:

- Sodium
- Potassium
- Chloride
- TCO_2
- BUN/Urea
- Creatinine
- Glucose
- Ionized Calcium

Each level of control is packaged in a box of 10 ampules with a sheet with target values and acceptable ranges. Control solutions are contained in 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but do contain buffers and preservatives.

Reactive Ingredients

Analyte	Calibration Verification Level 1	Calibration Verification Level 1b	Calibration Verification Level 2 and Control Level 1	Calibration Verification Level 3 and Control Level 2	Calibration Verification Level 4 and Control Level 3	Calibration Verification Level 5
Na (mmol/L)	102	102	120	134	160	178
K (mmol/L)	2.20	2.20	2.90	3.90	6.50	8.00
Cl (mmol/L)	70	70	82	95	118	133
Glu (mmol/L)	1.8	1.8	2.5	7.3	17	35
Urea (mmol/L)	45	45	18	4	2.7	1.9
iCa (mmol/L)	2.50	2.50	1.60	1.26	0.80	0.35
Crea (µmol/L)	1477	1477	386	154	46	17
PCO_2 (mmHg)	90	95	66	30	22	18
H^+ (pH)	6.550	6.060	7.005	7.410	7.660	7.920

Storage

Refrigerated storage at 2 to 8 °C (35 to 46 °F) should be maintained until the printed expiration date on the box and ampule labels.

Control solutions may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86 °F). Prolonged storage at temperatures greater than 30 °C (86 °F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Best Results

For best results, ampules, cartridges and analyzer should be at the same temperature.

Ampule Use

A separate ampule must be used for each cartridge being tested.

Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges.

Before Use

Equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.

Procedure

STEP	ACTION
1	Access the i-STAT Cartridge Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout) to insert the cartridge after the last data entry.
2	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4	Immediately transfer the solution from the ampule into a capillary tube or syringe, and then immediately transfer the solution into a cartridge.
5	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results. Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule to avoid drawing air into the capillary tube. Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer an aqueous control from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringe with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Target Values

Target values (determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included with each box of control ampules.

Always be sure that the lot number printed on the insert matches the lot number on the label of the ampule in use, and that the software revision above the target value table matches the software revision in the analyzer.

Ranges

The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly.

Should results outside the ranges be obtained, refer to the Troubleshooting section that follows the Procedure for Testing Controls.

Target Values are specific to the i-STAT System. Results obtained from these aqueous controls with other methods may differ due to sample matrix effects.

RNA® MEDICAL HEMATOCRIT CONTROL

Intended Use

RNA Medical Hematocrit Control is a quality control material used for verifying the performance of hematocrit sensors in i-STAT cartridges.

Product Description

Hematocrit controls are provided in three (3) levels for monitoring cartridge performance at different points within the clinical range. The controls are packaged in sealed glass ampules, each containing 1.7 mL of solution. Ampules are packaged ten (10) per box.

Active Ingredients

This product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. This control contains no red blood cells, and no human or biological material.

Storage

RNA Medical Hematocrit Control is stable until the expiration date stated on the ampule when stored at temperatures of 2-25 °C. Do not freeze or expose ampules to temperatures greater than 30 °C.

If stored refrigerated, the control material should be equilibrated to room temperature for at least four (4) hours prior to testing.

The product may turn slightly yellow in color over its shelf life if stored at room temperature. This coloration is normal and does not affect product performance.

Directions For Use

For each lot of i-STAT cartridges received, use a representational number of cartridges to analyze multiple levels of RNA Medical Hematocrit controls.

1. Gently invert the ampule to mix the solution. Tap the ampule to restore the liquid to the bottom of the ampule.
2. Open the ampule by snapping off the tip at the neck. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
3. Fill and seal a cartridge and insert immediately into the analyzer.
    i. Note: The Control option from the Quality Tests menu must be used on the i-STAT 1 Analyzer for RNA Medical Hematocrit Control.
4. Compare the i-STAT System Hematocrit result to the package insert value. If the result is within the expected range, use the cartridges as needed.
    i. If the results are outside of the expected range, consult page 14-20 of this sectionl for troubleshooting recommendations.

ii. Note: this product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. The only value assigned to this fluid is for hematocrit. All other cartridge analyte results obtained with this control material should be ignored.

5. If available, transmit results to the Central Data Station.

METER TRAX™ CONTROLS FOR HEMATOCRIT SENSOR

Meter Trax™ Whole Blood Reference Control for Glucose, Hemoglobin and Hematocrit (Meter Trax is a trademark of Hematronix, Inc., now BIO-RAD) is recommended as a control solution for the hematocrit sensor. Meter Trax is available in three levels: Low, Mid and High in boxes of one level (6x2mL) or boxes of three levels (6x2mL or 3x2mL).

The Quality Test option under the Administration Menu must be used when testing this control and only the hematocrit result will be reported.

CONTROLS FOR ACT CARTRIDGES

Intended Use

The i-STAT® ACT Control Level 1 and ACT Control Level 2 are intended for use to verify the integrity of newly received i-STAT ACT cartridges. The controls produce clotting times expected for moderate and high level heparinization to indicate that the cartridges are functioning properly.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of 9.5 ± 1.5 mmol/L calcium chloride diluent.

Storage

i-STAT ACT controls, Levels 1 and 2, are contained in 6-mL vials. Separate 6-mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8°C (35 to 46°F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30°C or 64 to ˉ86°F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature (18 - 30°C or 64 - 86°F) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note:** To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard the reconstituted fluid and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the ACT cartridge
6	Immediately seal the cartridge and insert it into an analyzer. **Note:** Additional ACT cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included in each box of control vials. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

CONTROLS FOR PT/INR CARTRIDGES

Intended Use

The i-STAT® PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used to verify the integrity of newly received PT/INR cartridges.

Contents

Each level of control is packaged as a box of 5 vials of lyophilized human plasma and 5 vials of calcium chloride diluent. The Level 1 control vials contain 9.5 ± 1.5 mmol/L calcium chloride, while the Level 2 control vials contain 12 ± 2.0 mmol/L calcium chloride.

Storage

i-STAT PT controls, Levels 1 and 2, are contained in 6-mL vials. Separate 6-mL vials contain 1-3 mL of calcium chloride solution for reconstitution. Refrigerated storage at 2 to 8°C (35 to 46°F) should be maintained until the printed expiration date on the box and vial labels. Do not use beyond the expiration date on the box and vial labels.

Control solutions may also be stored at room temperature for up to 4 hours (18 to 30°C or 64 to ˉ86°F). If left out longer than 4 hours at room temperature, they should be discarded.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Directions for Use

Prior to testing, vials containing the lyophilized plasma and $CaCl_2$ reconstituting fluid should stand at room temperature 18-30ºC (64-86ºF) for a minimum of 45 minutes. For best results, vials, cartridges, and analyzers should be at the same temperature.

Reconstitute only one level of control plasma at a time. CONTROL SOLUTIONS MUST BE USED IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

STEP	ACTION
1	After 45 minute room temperature equilibration, remove the cap and stopper from one lyophilized human plasma control vial and remove the cap from one vial of calcium chloride reconstituting fluid.
2	Pour the entire contents of the calcium chloride vial into the lyophilized human plasma control vial. Place the stopper back in the reconstituted control vial, sealing the vial appropriately so that the contents do not leak or spill out.
3	Allow the vial to sit at room temperature for 1 minute.
4	Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds. **Note**: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion. Visually inspect the control vial to ensure that the sample is fully reconstituted. If not, discard and start over with fresh vials.
5	Using a plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant, immediately transfer the solution from the vial into the PT/INR cartridge.
6	Immediately seal the cartridge and insert it into an analyzer. **Note**: Additional PT/INR cartridges may be tested with the remaining fluid if used within 30 seconds of complete reconstitution of the sample.

Control Target Values and Expected Ranges

Target values (determined by testing multiple vials of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) are printed on a value assignment sheet included in each box of control vials. The ranges displayed represent the maximum deviation expected when controls and cartridges are performing properly. Should results outside the range be obtained, refer to the Troubleshooting portion of this section of the i-STAT System Manual. Always be sure that the lot number printed on the value assignment sheet matches the lot number on the label of the vial in use, and that the software revision above the table matches the software revision in the analyzer (check the status page on the analyzer).

Note: Target values are specific to the i-STAT System; results obtained from these reconstituted control plasmas may differ if used with other methods.

CONTROLS FOR cTnI CARTRIDGES

Intended Use

i-STAT® Cardiac Markers Controls are assayed human sera used to verify the integrity of newly received i-STAT cTnI cartridges.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human sera used in the preparation of this product have been tested by FDA approved test methods and found negative/ non-reactive for HIV-1, HIV-2, HBsAg, HCV, HTLV-1 and HTLV-2. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Each vial contains < 0.1% sodium azide as a preservative. Dispose of this product according to all local, state and national regulations. If disposed down a drain, the sodium azide in this product may react with lead and copper plumbing to form highly explosive metal azides. Flush drain with large amounts of water to prevent azide build-up.

Do not use if the controls arrive thawed or uncapped.

Bacterial contamination can cause an increase in turbidity. Do not use the control if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Store at ≤ –18°C (-1 °F) in a non-defrosting freezer. After thaw, the opened or unopened vial is stable for 4 hours when capped and stored at 2-8°C (35-46 °F). Do not re-freeze.

Procedure

Step	Action
1	Remove vial from freezer and thaw at room temperature (18-30°C) for 15 minutes.
2	Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.
3	Dispense a drop of sample directly from vial into the i-STAT cTnI cartridge and seal the cartridge. Tightly recap the bottle immediately after all sampling is complete and store at 2-8°C.
4	Insert cartridge into an i-STAT analyzer.

Control Target Values and Ranges

See accompanying value assignment sheet. The value assignment sheet displays target values and ranges expected when controls and equipment are performing properly. Should results fall outside the range, refer to the System Manual.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

CLINIQA LIQUID QC™ CARDIAC MARKER CONTROLS FOR i-STAT

Intended Use

CLINIQA Liquid QC™ Cardiac Marker Controls are assayed human plasma which can be used to verify the integrity of newly received i-STAT CK-MB cartridges. CLINIQA Liquid QC Cardiac Marker Controls are not intended to be used as a standard.

Warning and Precautions

Each serum/plasma donor unit used in the manufacture of this product has been tested by FDA accepted methods and found negative/non-reactive for the presence of HBsAg and the antibody to HIV-1/2, HCV, and HIV-1 Ag. While these test methods are highly accurate, they do not guarantee that all infected units will be detected. Because no known test method can offer complete assurance the hepatitis B virus, hepatitis C virus, human immunodeficiency virus (HIV) or other infectious agents are absent, all products containing human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

CLINIQA Liquid QC Cardiac Marker Control is a ready-to-use liquid control requiring no reconstitution or frozen storage. It is stable until the expiration date on the vial label when stored unopened at 2-8°C. Once opened, ClLINIQA Liquid QC Cardiac Marker Control is stable for 30 days when stored tightly capped at 2-8°C.

Procedure

1. Access the i-STAT Cartridge Control option under Quality Tests in the Administration Menu. Enter the required information. The analyzer allows 15 minutes (or the customized timeout period) to insert the cartridge after the last data entry.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of the solution into the i-STAT CK-MB cartridge using a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8°C.
4. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.

Target Values and Ranges

See value assignment sheet accompanying the control material. The value assignment sheet displays target values and ranges expected when materials and equipment are performing properly. Should results fall outside the range, consult page 14-21 of this section for troubleshooting recommendations.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

i-STAT BNP CONTROLS (LEVELS 1, 2, AND 3)

Intended Use

i-STAT BNP Controls are assayed liquid plasma used to verify the integrity of newly received i-STAT BNP cartridges.

Warning and Precautions

Handle the products using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of these products has been tested by FDA approved test methods and found negative/non-reactive for HIV-I, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Each 1.0 mL vial contains <0.1% sodium azide as a preservative. Dispose of this product according to local, state, and national regulations. If disposed down a drain, the sodium azide in this product may react with lead and copper plumbing to form highly explosive metal azides. Flush drain with large amounts of water to prevent azide build-up.

Do not use if the controls arrive thawed or uncapped.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the control material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Store at ≤ -18°C (-1°F) in a non-defrosting freezer. After thawing, the opened or unopened vial is stable for 4 hours when capped and stored at 2-8°C (35-46°F). Do not re-freeze.

Procedure

1. Remove vial from freezer and thaw at room temperature (18-30°C) for 15 minutes.
2. Gently invert the vial 10 times, then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
3. Open the vial and transfer a drop of solution directly from the vial into the BNP cartridge and seal the cartridge. If short-term storage (<4 hrs) is desired, tightly recap the bottle immediately after all sampling is complete, and store at 2-8°C.
4. Insert cartridge into an i-STAT 1 Analyzer.

Target Values and Ranges

See value assignment sheet accompanying the control material. The value assignment sheet displays target values and ranges expected when controls and equipment are performing properly. Should results fall outside the range, refer to the Quality Control section of the i-STAT 1 System Manual.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

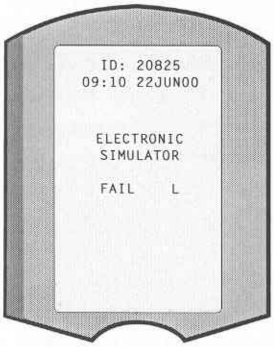
Target values are specific to the i-STAT System. Results may differ if used with other methods.

PERFORMING ELECTRONIC SIMULATOR TEST

Procedure for Internal Electronic Simulator

The internal Electronic Simulator test cycle is automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays "ELECTRONIC SIMULATOR FAIL." If the analyzer is customized to block testing when it fails the simulator test, the same cartridge can be re-inserted immediately after the FAIL message is displayed. If the analyzer fails the simulator test again, see the Troubleshooting section that follows the Procedure. If less than three minutes has elapsed, the cartridge can be inserted into another analyzer. If the analyzer is not customized to block testing after a failed simulator test, the internal simulator test will not repeat until the programmed interval has elapsed.

PROCEDURE FOR EXTERNAL ELECTRONIC SIMULATOR



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ELECTRONIC
SIMULATOR

FAIL L

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key to turn the analyzer on.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests Menu	Press **4** to select Simulator.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID and press **Enter**.	If enabled, the analyzer will validate ID and/or ask for the ID to be repeated.
Scan or Enter Simulator ID	Press **Scan** to scan the Simulator ID or manually enter the Simulator ID and press **Enter**.	The simulator serial number can be used as an ID. If the simulator does not have a barcode, one can be made on-site and affixed to the simulator (not near contact pads).
INSERT SIMULATOR	Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.	Inserting the simulator at an angle may cause a Quality Check message to be displayed.
Contacting Simulator Please wait... Time to Results bar Simulator Locked	Do not attempt to remove the simulator until the results are displayed and the "Simulator Locked" message is removed.	
Result screen: ID of Simulator Date and Time ELECTRONIC SIMULATOR PASS or FAIL 1 - Test Options	Test Options Simulator 1 - Next Simulator 2 - Same Simulator 3 - History	If **PASS** is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case. If **FAIL** is displayed, see the Troubleshooting in this section of the manual.

Caution

The analyzer will continue to initialize test cycles when the analyzer is customized to warn, but not block testing when a scheduled external Electronic Simulator test is missed, when a FAIL result for the external Electronic Simulator test is ignored, and when the analyzer fails the internal Electronic Simulator test and the lockout feature is not enabled.

TROUBLESHOOTING FAILED ELECTRONIC SIMULATOR TEST

Introduction

With both the internal and external Electronic Simulator, an analyzer may occasionally fail a simulator test even though it is in proper operating condition due to the extremely sensitive nature of the test.

External Simulator

Run the test again or try another simulator, as it is possible that the test will pass on a second try. The test can also fail if the external Electronic Simulator is malfunctioning such as after being dropped.

Occasionally when an analyzer is moved from a cold environment to a warm, humid environment, moisture may condense on the internal connector. An analyzer in this condition will fail the electronic test and the failure code "L" will be displayed. Allow the analyzer to sit for half an hour to allow the moisture to evaporate, then insert the Electronic Simulator again. If the analyzer passes the second electronic test, continue using it. If the analyzer fails the second time, record the letter or Quality Check Code displayed with the FAIL message and refer to Support Services information in the Troubleshooting section.

Internal Simulator

The cartridge or an external Electronic Simulator should be rerun to confirm the failure. The analyzer's connector pins are in contact with the biosensor chips in the cartridge being tested when the internal Electronic Simulator test is being performed. The test can fail if the contact pads have been contaminated in some way.

Lockout Enabled: Rerun the cartridge in the same analyzer to ensure the FAIL was not due to a one-time spike of electrical noise. If the test fails again, rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. If the cartridge fails in more than one analyzer, use another cartridge. When Lockout is enabled, the analyzer will continue to perform the internal Electronic Simulator test each time a cartridge is inserted until the test (internal or external) passes.

Lockout Not Enabled: Rerun the cartridge in another analyzer if immediately available. Note that the cartridge should not be run if there is more than a three minute delay from the time it is filled. When Lockout is not enabled, the analyzer will run the next cartridge without performing the internal Electronic Simulator test until the specified time has elapsed. Verify the analyzer using an external Electronic Simulator.

CHECKING THE THERMAL PROBES IN THE i-STAT ANALYZERS

Verification for Handheld Analyzers

Verify the thermal probe check for the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer as follows:

- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 4: On the CDS, click on **System**, then on **Simulator Results**. Look under the Delta column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.
- External Electronic Simulator used routinely and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Look under the Probe Delta column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each analyzer in use in the last 30 days. A value of "--.--" indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any analyzer that does not have a numeric value listed.
- External Electronic Simulator used routinely, results not transmitted to a Central Data Station: Use the procedure below to check the thermal probes on each analyzer twice a year.
- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each analyzer twice a year.

Procedure for Handheld Analyzers

Check the thermal probes on the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer as follows:

1. If the analyzer and simulator have been stored separately in areas where the ambient temperature differs by more than 3°C (5°F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. Insert the simulator into the analyzer.
3. When results are displayed, the difference between the thermal probes can be viewed on the analyzer's screen:
    - Portable Clinical Analyzer: while holding down the DIS key, press the 1 key.
    - i-STAT 1 Analyzer: press the period key.
4. Interpretation of the thermal probe check value:
    - Acceptable: a value equal to or less than 0.1 (≤ 0.1)
    - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
    - Repeat the procedure: if "--.--" is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.

Verification of BAMs

Verify the thermal probe check on a Philips Medical System Blood Analysis Module (BAM) and Central Data Station Version 5 as follows:

- External Electronic Simulator used daily and results transmitted to a Central Data Station Version 5: On the CDS, click on **Data Viewer**, then on **Simulator**. Click on **Record** in the Main Menu, then click on **Extended Electronic Simulator Report**. Look under the Pot6P column. Check that there is a value equal to or less than 0.1 (≤ 0.1) listed for each BAM in use in the last 30 days. No recorded value indicates that the conditions to complete the thermal probe check were not met. Use the procedure below to check any BAM that does not have a numeric value listed.
- Internal Electronic Simulator used routinely: Use the procedure below to check the thermal probes on each BAM twice a year.

Procedure for BAMS

Check the thermal probes on a BAM as follows:

1. Insert the simulator partially into the BAM and wait for 15 minutes before inserting the simulator all the way into the BAM. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
2. When results are displayed, transmit the results to the Central Data Station.
3. View the probe check value on the CDS:
   1) Click on Data Viewer
   2) Click on Simulator
   3) Click on Record in the Main Menu task bar
   4) Click on Extended Electronic Simulator Report
   5) Look under the Pot6P column
4. Interpretation of the thermal probe check value:
   - Acceptable: a value equal to or less than 0.1 (≤ 0.1)
   - Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm the results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
   - No value: repeat the procedure. Take care to handle the simulator as little as possible. It may help to increase the time in step 2 to 30 minutes.

Documentation of Results

The results of the The results of thermal probe check are stored in the Central Data Station. If the Central Data Station is not available, use the form included with this Technical Bulletin to record the results.

PROCEDURE TO CHECK AMBIENT TEMPERATURE

Place the analyzer in a room with a calibrated thermometer suspended near the analyzer and away from air currents for one hour. Check the temperature reading on the Analyzer Status page under the Administration Menu. The temperature reading should be ± 1 °C of the thermometer's reading.

PERFORMING CONTROL TEST ON CARTRIDGE

Procedure for Testing Controls

Initiating control tests from the Quality Test Menu allows results to be stored in separate categories for the purpose of documentation and review.

NOTE:

RNA Medical Controls and BIO-RAD Meter Trax controls **must** be tested using this control path and not as a patient sample.

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests 1 – Control 2 – Proficiency 3 – Cal Ver 4 – Simulator	Press **1** to select Control.	
Quality Tests Control 1 – i-STAT Cartridge 2 – PCx Glucose Strip	Press **1** to select i-STAT Cartridge.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Control Lot Number	Press **Scan** to scan the Control Lot Number or manually enter the Lot Number using the keypad and press **Enter**.	
Scan or Enter Cartridge Lot Number	Press **Scan** to scan the Cartridge Lot Number or manually enter the number using the keypad and press **Enter**.	
INSERT CARTRIDGE		The analyzer will display INSERT CARTRIDGE for 15 minutes (or a customized timeout, whichever is greater) before turning off.
Identifying Cartridge Please wait… Cartridge Locked		Do not attempt to remove the cartridge while the "Cartridge Locked" message is displayed.

PERFORMING CONTROL TEST ON CARTRIDGE (CONTINUED)

Display	Step	Analyzer Response / Comments
i-STAT (Cartridge panel number) Time to Results → Page Cartridge Locked	If enabled, the Chart page will be displayed automatically. If not, press the → kewy to go to the Chart page if necessary.	
Control (lot number) Scan or Enter Data Control Level _ Field 1 --------- Field 2 --------- Field 3 --------- → Page Cartridge Locked	Scan or manually enter the control level (such as 1, 2 or 3) and press Enter. The screen has three fields with capacity for 9 characters each. These fields can be used for additional information. Press the **Enter** key to move from field to field and to edit. Use the ← key to backspace and erase entered characters.	Operator Test Selection is not enabled for control tests. Tests disabled in customization will not be displayed. Information entered on the Chart and Test Selection page can be changed up until: • the next test is initiated. • results are transmitted. • the **Menu** key is used to backup to the Test Menu screen. • a Test Option is selected.
Results 1-Test Options	Test Options Control 1 - Next Level 2 - Repeat Level 3 - History	The "Cartridge Locked" message is removed and the cartridge may be removed.

TROUBLESHOOTING OUT-OF-RANGE CONTROL RESULTS ON CARTRIDGE

Troubleshooting

Verify that the following conditions are met and then repeat the test:

- The correct expected values insert is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly: See the directions for use.
- The analyzer being used passes the Electronic Simulator test.

If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or cartridges. If the results are still out of range, refer to Support Services information in the Troubleshooting section.

CONTROLS FOR GLUCOSE TEST STRIP

Control Solutions

Use only Precision™, Precision·G®, or MediSense® Control Solutions to verify the performance of the Precision PCx and PCx Plus Test Strips and the test strip reading function of the analyzer. Controls contain a known amount of glucose.

Storage

Control Solutions should be stored at temperatures between 4 and 30 °C (39 to 86 °F).

Do not use control solutions after the expiration date printed on the bottles and the box. The analyzer does not accept control solutions that have passed their expiration date.

Each bottle of control solutions is stable for 90 days after opening if cap is replaced tightly after each use. Discard all unused solutions 90 days after opening.

Directions for Use

When opening a new bottle, write the current date on the bottle label.

Invert the control solution bottle several times to ensure thorough mixing before use.

Invert and tap the capped control solution bottle to remove air bubbles from the nozzle of the bottle.

Replace the cap on the bottle and tighten the cap immediately after each use.

Barcode

Do not scan one test strip packet's barcode and use a test strip from another packet. This may cause incorrect assay results to be generated.

RECOMMENDATIONS FOR GLUCOSE TEST STRIPS

When to Test Controls

- Daily.
- When you question blood glucose results.
- When you adjust diabetes medication plans.
- When your test strips have been exposed to temperatures outside the storage conditions (39°-86 °F, 4°-30 °C).
- When you open a new lot of test strips.

PERFORMING CONTROL TEST WITH GLUCOSE STRIP

Procedure

If the analyzer displays a message not indicated in this procedure, refer to Troubleshooting Section of this Manual.

Caution

Allow the analyzer to remain completely horizonal while testing controls to prevent control fluids from running into the test strip port.

Display	Step	Analyzer Response / Comments
	Press the **On/Off** key.	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key.	Controls can also be run from the test menu.
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests 1 – Control 2 – Proficiency 3 – Cal Ver 4 – Simulator	Press **1** to select Control.	
Quality Tests Control 1 – i-STAT Cartridge 2 – PCx Glucose Strip	Press **2** to select PCx Glucose Test Strip.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID barcode, or manually enter the Operator ID via the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Low Level Control Lot Number	Scan or manually enter the Low Level Control Solution Lot Number via the keypad and press **Enter**.	The analyzer expects controls to be tested in order of Low, Mid (if enabled), High. If the Unexpected Level screen appears, press **1** - Re-enter to enter the correct level lot number, or press 2 to continue to test the unexpected level.
Scan or Enter Strip Lot Number	Scan or manually enter the Test Strip Lot Number.	Messages that can be enabled in Customization: Invalid Number, Invalid Length, Lot Expired.

PERFORMING CONTROL TEST WITH GLUCOSE STRIP (CONTINUED)

Display	Step	Analyzer Response / Comments
INSERT STRIP	Open the foil test strip packet at the notch and tear up or down to remove the test strip. With the contact bars facing up, insert the test strip into the test strip port until it stops.	The analyzer will display INSERT CARTRIDGE for 15 minutes (or a customized timeout, whichever is greater) before turning off.
Apply Low Control Sample	Gently invert the control solution bottle 3-4 times then apply a drop to the target area on the test strip.	The analyzer beeps when the sample is accepted. Recap the control solution bottle tightly.
Sample Accepted		
Precision PCx Blood Glucose Strip Time to Results → Page	If Auto-Chart is enabled, the Chart page will be displayed automatically. The Chart page can be displayed by pressing the right arrow key.	There are three free field lines, each of which can accept up to 9 characters. The analyzer counts down 20 seconds then displays the test result.
Results 1 – Test Options	Test Options Control 1 – Next Level 2 – Repeat Level 3 – History	Results are displayed as **PASS** or **FAIL** (according to the ranges encoded in the test strip lot number or programmed into the analyzer through the Customization function on the Central Data Station) and numerically. If Comment Code is enabled, the analyzer will request the operator to **Scan** or **Enter** a Comment Code. Up to 3 characters can be entered.
Remove Strip		Repeat the procedure for the Mid Level Control, if enabled, and the High Level Control. If the Next Test option is selected, the analyzer will prompt for the High Control (or Mid Control if enabled.)

TROUBLESHOOTING OUT-OF-RANGE RESULTS ON TEST STRIPS

Troubleshooting

Repeat the test for that control solution and verify that the following conditions are met:

- No air bubbles are in the control bottle's nozzle.
- Calibrate the monitor using the barcode for the test strip used.
- Enter the correct 5-digit lot number for the control solution.
- Check storage temperatures: Solutions and test strips must be stored between 39 °F and 86 °F (4 °C and 30 °C).
- Check that the temperature and humidity conditions in the room where the tests are being performed are within the acceptable operating range.
- Check that the bottles have not been opened for more than 90 days.
- Use a new test strip for each test.
- Use only Precision PCx or PCx Plus Test Strips.

If test results are out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or test strips. If results are still out of range refer to Support Services information in the Troublshooting section.

i-STAT System Incoming Cartridge QC Log

Catridge Type:______ **Lot No.:**______ **Rec'd Date:**______ **Exp. Date:**______ **Quat:**______ **Temp. Strip*:**______

Control Name: ______ **Level:** ______ **Lot No.:** ______ **Exp. Date:** ______

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ______ **Level:** ______ **Lot No.:** ______ **Exp. Date:** ______

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ______ **Level:** ______ **Lot No.:** ______ **Exp. Date:** ______

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

Control Name: ______ **Level:** ______ **Lot No.:** ______ **Exp. Date:** ______

TEST	TEST	TEST	TEST	TEST	TEST	TEST	TEST
RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE	RANGE

i-STAT System QC Log: Expiration Date and Storage Conditions

				REFRIGERATED 2 TO 8° C (35 TO 46° F)			REFRIGERATED 2 TO 8° C (35 TO 46° F)				
DATE	**LOCATION**	**CARTRIDGE TYPE**	**LOT #**	**QTY**	**EXP. DATE**	**TEMP**	**QTY**	**EXP. DATE**	**TEMP**	**ACTIONS**	**INSP.**

i-STAT Cartridge Quality Control Action Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	CARTRIDGE LOT	PROBLEM	CORRECTIVE ACTION	OPERATOR

i-STAT Analyzer PCx and PCx Plus Glucose Test Strip QC Log

DATE	TIME	CONTROL LEVEL	CONTROL LOT	STRIP LOT	PASS FAIL	IF FAIL EXPECTED RANGE	RESULT	ACTION	OPERATOR

i-STAT Electronic Simulator Log for Analyzer Serial Number:________ Year:________

DATE	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR	TIME	PASS FAIL	SIMULATOR ID	OPERATOR

i-STAT Electronic Simulator Action Log

DATE	TIME	ANALYZER	FAILURE CODE OR LETTER	SIMULATOR ID	ACTION	OPERATOR

i-STAT Analyzer Thermal Probe Check

Year: ________

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

Analyzer Serial No.: ____________________

DATE	SIMULATOR SERIAL NO.	THERMAL PROBE DELTA RESULT (LIMIT: ± 0.1° C)	COMMENTS	OPERATOR

CALIBRATION VERIFICATION 15

CALIBRATION VERIFICATION FOR BLOOD GAS/ELECTROLYTE/METABOLITE CARTRIDGES (EXCEPT CHEM8+ CARTRIDGES)

Purpose

Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While the Calibration Verification Set contains five levels, verification of the measurement range could be accomplished using the lowest, highest and mid levels.

Overview of Procedure

i-STAT recommends that each sensor type be included in the Calibration Verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solutions for Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT cartridges throughout the reportable ranges for:

Sodium
Potassium
Chloride
Ionized Calcium

pH
PCO_2
PO_2

Glucose
Lactate
BUN/Urea
Creatinine

There are four 1.7mL glass ampules of each level in the set.

Reactive Ingredients

See the table on page 14-3 of the Quality Control section for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46°F) should be maintained until the printed expiration date on the box and ampule labels. Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86°F). Prolonged storage at temperatures greater than 30 °C (86°F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

If stored refrigerated, the control material should be equilibrated to room temperature for at least four (4) hours prior to testing.

Ampule Use

When using cartridges that contain sensors for pH, PCO_2, PO_2 and ionized calcium, a separate ampule must be used for each cartridge being tested. If these sensors are not present, the contents of one ampule may be used to fill more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

i-STAT CALIBRATION VERIFICATION SET

Before Use

i-STAT Calibration Verification solutions require different temperature stabilization times depending on whether or not oxygen is to be measured. If oxygen is to be measured, equilibrate the ampule to room (ambient) temperature for 4 hours. If not, equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) and acceptable ranges are printed on a Value Assignment Sheet included with each Calibration Verification Set.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If the result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

Note: If the Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the Calibration Verification Set are not intended or prepared to be equally spaced.

If testing at extreme altitude refer to Correction of PO_2 at Extreme Altitude under Controls for Blood Gas/Electrolyte/Metabolite Cartridges in the Quality Control section of the manual.

i-STAT CHEM8+ CALIBRATION VERIFICATION SET

Overview of Procedure

i-STAT recommends that each sensor type be included in the Calibration Verification procedure using a selection of analyzers that have passed the Electronic Simulator check. See the Technical Bulletin "Calibration Verfication and the i-STAT System" for more information.

Calibration Verification Solutions for CHEM8+ Cartridges

A five-level Calibration Verification Set is available to verify the calibration of i-STAT CHEM8+ cartridges throughout the reportable ranges for:

Sodium	TCO_2	Glucose
Potassium	BUN/Urea	Creatinine
Chloride	Ionized Calcium	

There are four 1.7mL glass ampules of each level in the set.

An additional i-STAT CHEM8+ Calibration Verification Level 1b is available for purchase to verify the calibration of the i-STAT CHEM8+ TCO_2 at the low end of the reportable range.

Reactive Ingredients

See the table on page 14-6 of the Quality Control section for full information.

Storage

Refrigerated storage at 2 to 8 °C (35 to 46°F) should be maintained until the printed expiration date on the box and ampule labels. i-STAT CHEM8+ Calibration Verification fluids may also be stored at room temperature for up to 5 days (18 to 30 °C or 64 to 86°F). Prolonged storage at temperatures greater than 30 °C (86°F) may cause changes in the values of some analytes. Do not use beyond the expiration date on the box and ampule labels.

Ampule Use

A separate ampule must be used for each cartridge being tested.

Best Results

For best results, ampules, cartridges and analyzers should be at the same temperature.

Before Use

Equilibrate the ampule to room (ambient) temperature for 30 minutes.

Procedure

STEP	ACTION
1	Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
2	Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3	Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
4	Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.

Note: Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Transfer with Capillary Tube

Plain capillary tubes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a capillary tube (fresh capillary tubes with sufficient fill capacity are recommended), fill from the bottom of the ampule.

Avoid drawing solution from the surface by placing a finger over the far end of the tube as it is inserted into the ampule.

Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.

Transfer with Syringe

Plain syringes are recommended to transfer aqueous calibration verification material from the ampule to the cartridge. When using a syringe (fresh 1cc or 3cc sterile syringes with 16 - 20 gauge needles are recommended), slowly draw approximately 1mL of solution from the bottom of the ampule.

If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the front of the syringe.

If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe.

Expel one or two drops from the syringe before filling the cartridge.

Acceptable Criteria

Target values (determined by testing multiple ampules of each level using multiple lots of i-STAT cartridges with analyzers that have passed the Electronic Simulator test) and acceptable ranges are printed on a Value Assignment Sheet included with each i-STAT CHEM8+ Calibration Verification Set.

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If the result for a level is outside the range published in the Value Assignment Sheet, two additional cartridge runs should be performed on this level and the three results averaged and then compared to the Value Assignment Sheet range. If this average value is still outside the acceptable range, troubleshooting may be required.

Note: If the i-STAT CHEM8+ Calibration Verification Set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the i-STAT CHEM8+ Calibration Verification Set are not intended or prepared to be equally spaced.

i-STAT CARDIAC MARKER CALIBRATION VERIFICATION SET

A three level Calibration Verification Set is available to verify the calibration of cTnI cartridges throughout the reportable range.

There are two 1.0 mL plastic vials of each level in the set.

Intended Use

i-STAT® Cardiac Markers Calibration Verification Controls are assayed human sera used to verify the calibration of the cTnI test throughout the reportable range.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human sera used in the preparation of this product have been tested by FDA approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, HCV, HTLV-1 and HTLV-2. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Each vial contains < 0.1% sodium azide as a preservative. Dispose of this product according to all local, state and national regulations. If disposed down a drain, the sodium azide in this product may react with lead and copper plumbing to form highly explosive metal azides. Flush drain with large amounts of water to prevent azide build-up.

Do not use if the controls arrive thawed or uncapped.

Bacterial contamination can cause an increase in turbidity. Do not use the control if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Store at ≤ –18°C (-1°F) in a non-defrosting freezer. After thaw, the opened or unopened vial is stable for 4 hours when capped and stored at 2-8°C (35-46°F). Do not re-freeze

Procedure

Step	Action
1	Remove vial from freezer and thaw at room temperature (18-30°C) for 15 minutes.
2	Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.
3	Dispense a drop of sample directly from vial into the i-STAT cTnI cartridge and seal the cartridge. Tightly recap the bottle immediately after all sampling is complete and store at 2-8°C.
4	Insert cartridge into an i-STAT analyzer.

Control Target Values and Ranges

See accompanying value assignment sheet. The value assignment sheet displays target values and ranges expected when controls and equipment are performing properly. Should results fall outside the range, refer to the System Manual.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

i-STAT BNP CALIBRATION VERIFICATION CONTROL (LEVELS 1, 2, AND 3)

Intended Use

i-STAT BNP Calibration Verification Controls are assayed liquid plasma used to verify the calibration of the BNP test throughout the reportable range.

Warning and Precautions

Handle the products using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of these products has been tested by FDA approved test methods and found negative/non-reactive for HIV-I, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Each 1.0 mL vial contains <0.1% sodium azide as a preservative. Dispose of this product according to local, state, and national regulations. If disposed down a drain, the sodium azide in this product may react with lead and copper plumbing to form highly explosive metal azides. Flush drain with large amounts of water to prevent azide build-up.

Do not use if the calibration verification materials arrive thawed or uncapped.

Bacterial contamination of the control can cause an increase in turbidity. Do not use the calibration verification material if there is visible evidence of microbial growth or gross contamination.

Storage and Stability

Store at ≤ -18°C (-1°F) in a non-defrosting freezer. After thawing, the opened or unopened vial is stable for 4 hours when capped and stored at 2-8°C (35-46°F). Do not re-freeze.

Procedure

1. Remove vial from freezer and thaw at room temperature (18-30°C) for 15 minutes.
2. Gently invert the vial 10 times, then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
3. Open the vial and transfer a drop of solution directly from the vial into the BNP cartridge and seal the cartridge. If short-term storage (<4 hrs) is desired, tightly recap the bottle immediately after all sampling is complete, and store at 2-8°C.
4. Insert cartridge into an i-STAT 1 Analyzer.

Target Values and Ranges

See value assignment sheet accompanying the calibration verification material. The value assignment sheet displays target values and ranges expected when controls and equipment are performing properly.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods.

RNA® MEDICAL HEMATOCRIT CALIBRATION VERIFICATION CONTROLS

Intended Use

RNA Medical Hematocrit Calibration Verification Control is a quality control material used for verifying the calibration and linearity of hematocrit sensors in i-STAT cartridges.

Product Description

Hematocrit Calibration Verification Controls are provided in five (5) levels for verifying the accuracy of hematocrit measurements throughout the reportable range. The controls are packaged in sealed glass ampules, each containing 1.7 mL of solution. Ampules are packaged in kits containing four (4) ampules of each level.

Active Ingredients

This product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. This control contains no red blood cells, and no human or biological material.

Storage

RNA Medical Hematocrit Calibration Verification Control is stable until the expiration date stated on the ampule when stored at temperatures of 2-25 °C. Do not freeze or expose ampules to temperatures greater than 30 °C.

If stored refrigerated, the calibration verification material should be equilibrated to room temperature for at least four (4) hours prior to testing.

The product may turn slightly yellow in color over its shelf life if stored at room temperature. This coloration is normal and does not affect product performance.

Directions For Use

1. Beginning with Level 1, gently invert the ampule to mix the solution. Tap the ampule to restore the liquid to the bottom of the ampule.
2. Open the ampule by snapping off the tip at the neck. Use gauze, tissue, gloves, or an appropriate ampule opener (a Snapper is included for this purpose) to protect fingers from cuts.
3. Fill and seal a cartridge and insert immediately into the analyzer.
    i. Note: The CalVer option from the Quality Tests menu must be used on the i-STAT 1 Analyzer for RNA Medical Hematocrit Calibration Verification Control.
4. Record the results on the Data Collection and Linearity Worksheet provided.
5. Test Levels 2, 3, 4, and 5 in the same manner. Record all values on the worksheet.
    i. Note: this product is a buffered aqueous solution containing electrolytes and non-conductive ingredients. The only value assigned to this fluid is for hematocrit. All other cartridge analyte results obtained with this control material should be ignored.

6. Compare the the i-STAT System Hematocrit result value for each level to the package insert value.
    - i. If your result is within the assigned value range, circle **Y** at the question **OK?**.
    - ii. If the result is outside of the expected range, run two (2) additional cartridges.
        - a. Report the mean of the three (3) results.
        - b. If your mean is within the assigned value range, circle **Y** at the question **OK?**.
        - c. If this result is also out of the expected range, circle **N** and contact i-STAT Technical Support at 1-800-366-8020, option 1.
7. If available, transmit results to the Central Data Station.

VERIFICATION PROCEDURE FOR HEMATOCRIT

Preparation of Hematocrit Samples

1. Draw 4 lithium heparin green top tubes from a fasting person with a normal hematocrit or MCHC. 7mL vacuum tubes are suggested. Label the tubes 1, 2, 3, and 4.
2. Centrifuge tubes 3 and 4 for 10 minutes at 3,000 rpm to pack the cells.
3. Remove two thirds the volume of whole blood from tube 1. This blood should be held in a clean plain tube in case it is needed to make adjustments later.
4. Transfer all of the plasma from tube 4 to tube 1.
5. Remove three fourths of the plasma from tube 3. This plasma should be held in a clean plain tube in case it is needed to make adjustments.
6. Gently invert tubes 1, 2 and 3 to resuspend the cells.
7. Measure the hematocrit of the blood in tubes 1, 2, and 3 using one cartridge for each tube. Adjust the hematocrit in tube 1 until it reads close to, but not less than, 10%. Adjust the hematocrit in tube 3 until it reads close to, but not more than, 75%.

Measurement

1. Gently invert tubes 1, 2, and 3 to resuspend the cells.
2. Measure the hematocrit of the blood in tubes 1, 2, and 3 three times each by the i-STAT and microcentrifuge methods.
3. Inspect the data for outliers. Repeat a measurement if necessary.
4. Calculate the mean of the three measurements of the three hematocrit levels for both methods.

Interpretation of Results

The i-STAT hematocrit method using blood anticoagulated with lithium heparin is calibrated to give results equivalent to the reference microhematocrit method using blood anticoagulated with K_3EDTA. Since the blood used for the microhematocrit determination here is anticoagulated with lithium heparin, adjustment must be made to the observed i-STAT values to compensate for the anticoagulant difference.

1. To calculate the adjusted i-STAT hematocrit mean, multiply the mean of the observed i-STAT results by 1.0425.
2. The adjusted i-STAT hematocrit mean should be within ±3%PCV of the microhematocrit mean.

For example: the microhematocrit method mean for the mid level sample is 36%PCV. The i-STAT method mean is 34%PCV. 34 x 1.0425 = 35.445. Acceptable range for the adjusted i-STAT mean: 33 - 39%PCV.

Note: If your analyzers are customized for K_2EDTA/Heparin/None, the above calculation is unneccessary.

Notes on the Procedure

1. If a higher hematocrit value is needed in tube 1 or 3, packed cells can be obtained by centrifuging the whole blood retained from tube 1 in step 3. If a lower hematocrit value is needed, add plasma retained in step 5.
2. The highest hematocrit that should be tested on the i-STAT System is 75%. Whole blood samples with hematocrit values greater than 75% will be flagged as >75. The lowest hematocrit that should be tested on the i-STAT System is 10%. Whole blood samples with hematocrit values less than 10% will be flagged as <10.

Using Another Comparative Method

Methods other than the reference microhematocrit procedure may be used to verify calibration and reportable range of the i-STAT hematocrit. However, the following requirements apply:

- Blood should be drawn from a fasting donor with a normal hematocrit and a normal MCHC (calculated from hemoglobin and hematocrit values determined using reference methods) and be free of specific interferences which degrade the accuracy and/or precision of the alternative comparative method or the i-STAT method.
- Calculation of results must correct for any systematic bias between the reference microhematocrit method and the alternative comparative method selected.

Reference Method

CLSI recommends that the blood samples anticoagulated with Na_2EDTA or K_2EDTA be used for the microhematocrit method.* However, EDTA will interfere with the electrolyte measurements which are used in the calculation of hematocrit results on the i-STAT System.

* CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method;* Approved Standard– Third Edition. NCCLS document H7-A3 (ISBN 1-56238-413-9). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

VERIFICATION PROCEDURE FOR ACT

See Technical Bulletin: i-STAT Celite and i-STAT Kaolin ACT Heparin Linearity Procedure

PROCEDURE FOR CARTRIDGES

Initiating Calibration Verification tests from the Quality Tests menu allows results to be stored in separate categories for the purpose of documentation and review. Also, measurement limits are not applied to results in this test path. Therefore, results below and above the measurement ranges will be reported.

Display	Action	Analyzer Response
	Press the **On/Off** key.	Logo briefly displayed followed by Test.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests 1 – Control 2 – Proficiency 3 – Cal Ver 4 - Simulator	Press **3** to select Cal Ver.	
Quality Tests Cal Ver 1 – i-STAT Cartridge 2 – PCx Glucose Strip	Press **1** to select i-STAT Cartridge.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Cal Ver Kit Lot Number	Press **Scan** to scan the Kit Lot Number or enter the Kit Lot Number using the keypad and press **Enter**. If a new Lot Number is entered, the message "New Panel Will Replace Old Panel" will be displayed with two options: 1 – ReEnter 2 – Replace Panel Press **1** to re-enter the lot number or **2** to replace the old lot number with the new lot number.	**Note:** The Calibration Verification Kit is not barcoded and does not have a Kit Lot Number. Each level has its own lot number. Enter the lot number of Level 1 as the Kit Lot Number. The analyzer stores the lot number of the kit in use. When a new kit lot number is entered, the counter for all levels will be set to zero.
Select Level 1 - Level 1 (0) 2 - Level 2 (0) 3 - Level 3 (0) 4 - Level 4 (0) 5 - Level 5 (0) 6 - Reset	Enter the number of the level to be tested.	The analyzer tracks how many replicates of each level are tested. Selecting **6 – Reset** resets the counters for all levels back to zero. Up to 4 replicates of each level can be tracked.

Display	Action	Analyzer Response
Scan or Enter Cartridge Lot Number	Press **Scan** to scan the Lot Number or manually enter the Cartridge Lot Number using the keypad and press **Enter**.	
INSERT CARTRIDGE Identifying Cartridge Please wait... Cartridge Locked		Operator Test Selection is not enabled for calibration verification tests. Tests disabled in customization will not be displayed.
i-STAT (Cartridge panel number) Time to Results → Page Cartridge Locked	If enabled, the Chart page will be displayed automatically. If not, press the → key to go to the Chart page if necessary.	
Results 1-Test Options	Test Options Cal Ver 1 - New Level 2 - Same Level 3 - History	The "Cartridge Locked" message is removed and the cartridge may be removed.

Troubleshooting Cartridge Tests

See Troubleshooting Out-of-Range Results for Cartridges paragraph in the Performing Control Tests on Cartridges section of this manual.

LINEARITY/CALIBRATION VERIFICATION TEST FOR TEST STRIPS

Linearity Solutions for Test Strips

Use the linearity kit supplied by Abbott. Instructions and acceptance criteria are included in the kit's package insert. Use the Precision PCx or PCx Plus values in the package insert for the strip reader in the i-STAT 1 Analyzer. The kit is not validated for use with cartridges. If the Point-of-Care Central Workstation includes a QC Manager Application, it will analyze the data.

Procedure for Test Strips

Initiating linearity tests from the Quality Tests menu allows results to be stored in separate categories for the purpose of documentation and review.

Caution

Allow the analyzer to remain completely horizontal while testing aqueous solutions to prevent solutions from running into the test strip port.

Display	Action	Analyzer Response
	Press the **On/Off** key.	Logo briefly displayed followed by Test.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests 1 – Control 2 – Proficiency 3 – Cal Ver 4 - Simulator	Press **3** to select Cal Ver.	
Quality Tests Cal Ver 1 – i-STAT Cartridge 2 – PCx Glucose Strip	Press **2** to select PCx Glucose Strip.	
Scan or Enter Operator ID	Press **Scan** to scan the Operator ID or manually enter the Operator ID using the keypad and press **Enter**.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Cal Ver Kit Lot Number	Press **Scan** to scan the Kit Lot Number or enter the Kit Lot Number using the keypad and press **Enter**. If a new Lot Number is entered, the message "New Panel xxx Will Replace Old Panel xxx" will be displayed with two options: 1 – ReEnter 2 – Replace Panel Press **1** to re-enter the lot number or **2** to replace the old lot number with the new lot number.	The analyzer stores the lot number of the kit in use. Entering a new kit lot number will automatically reset the counters for each level to zero.

LINEARITY/CALIBRATION VERIFICATION TEST FOR TEST STRIPS (CONTINUED)

Display	Action	Analyzer Response
Select Level 1 - Level 1 (0) 2 - Level 2 (0) 3 - Level 3 (0) 4 - Level 4 (0) 5 - Level 5 (0) 6 - Reset	Enter the number of the level to be tested.	The analyzer tracks how many replicates of each level are tested. Selecting **6 – Reset** resets the counters for all levels back to zero. Up to 4 replicates of each level can be tracked.
Scan or Enter Strip Lot Number	Scan the Strip Lot Number or enter the number using the keypad and press **Enter**.	
INSERT STRIP	Open the foil test strip packet at the notch and tear up or down to remove the test strip. With the contact bars facing up, insert the test strip into the test strip port until it stops.	
Apply Cal Ver Sample	Follow the manufacturers instructions for mixing the sample, and then apply a drop to the target area.	The analyzer beeps when the sample is accepted. Recap the solution bottle tightly.
Precision PCx Blood Glucose Strip Time to Results → Page	If Auto-Chart is enabled, the Chart page will be displayed automatically. The Chart page can be displayed by pressing the → key.	There are three free field lines, each of which can accept up to 9 characters. The analyzer counts down 20 seconds then displays the test result.
Results 1 – Test Options	Test Options Cal Ver 1 - New Level 2 - Same Level 3 - History	Repeat the procedure for replicates of the same level or for additional levels.
Remove Strip		

Troubleshooting Strip Tests

See the Troubleshooting Out-of-Range Results on Strips paragraph in the Quality Control section of this manual.

PROFICIENCY or EXTERNAL QUALITY CONTROL TESTING 16

Purpose

Samples from external quality control providers can be used to assess consistency of results for a particular method or system across testing sites. Due to matrix effects and additives, these samples should not be used as an indication of the system's true accuracy.

General Procedure

Initiating Proficiency Tests from the Quality Tests menu allows results to be stored in separate categories for the purpose of documentation and review. Proficiency samples should be tested in the same way as patient samples.

The same CLEW is used for the patient test path and the Proficiency test path. However, in the proficiency test path hematocrit results are calculated using coefficients for K3EDTA even if the analyzer is customized for K2EDTA. This ensures that hematocrit results are consistent across all sites. Also, if star-outs occur frequently when using the patient sample test path to test proficiency or external quality control samples, they might be avoided by using the proficiency test path.

Procedure For Cartridges

Display	Action	Analyzer Response
	Press the **On/Off** key.	Logo briefly displayed followed by Test.
Test Menu	Press the **Menu** key.	
Administration Menu	Press **3** to select Quality Tests.	
Quality Tests 1 – Control 2 – Proficiency 3 – Cal Ver 4 - Simulator	Press **2** for Proficiency.	
Quality Tests Proficency 1 – i-STAT Cartridge 2 – PCx Glucose Strip	Press **1** for i-STAT Cartridge.	
Insert Cartridge		
Scan or Enter Operator ID Cartridge Locked	Press **Scan** to scan the Operator ID or manually enter the number using the keypad and press **Enter**. Do not attempt to remove the cartridge while the "Cartridge Locked"message is displayed.	If enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Proficiency ID	Press **Scan** to scan the Proficiency ID or manually enter the characters that identify the sample and press **Enter**.	An ID of up to 15 characters can be entered.

Procedure For Cartridges (continued)

Display	Action	Analyzer Response
Scan or Enter Cartridge Lot Number	Press **Scan** to scan the Lot Number or manually enter the Lot Number and press **Enter**.	This screen is displayed if this option is enabled for patient testing.
Test Selection screen	If Test Selection is enabled, select the tests to be reported.	
i-STAT (Cartridge panel number) Time to Results → Page Cartridge Locked	If the Chart page is not automatically displayed, press the → key to enter information on the chart page.	
ID Scan or Enter Data Sample Type _ Field 1 --------- Field 2 --------- Field 3 --------- Pt Temp ----- FIO2 --- CPB NO 1-ART 4-CAP 2-VEN 5-CORD 3-MIX 6-OTHR → **Page** Cartridge Locked	Enter information if desired. Use the **Enter** key to move from field to field. For CPB the choices are: 1 – YES and 2 – NO. Default is NO. Use the → key to return to the results page	**Note:** For consistency across sites, it is recommended that NO be selected for CPB. **Note:** CPB is included on the screen only when the cartridge includes a sensor for hematocrit. Information entered on the Chart and Test Selection pages can be changed up until: • the next test is initiated. • results are transmitted. • the **Menu** key is used to backup to the Test Menu screen. • a test option is selected.
Results Comment 1 -Test Options	Enter a Comment Code if requested. Test Options Proficiency 1 - Next Sample 2 - Same Sample 3 - History	Tests disabled in customization will not be displayed. The "Cartridge Locked" message is removed and the cartridge may be removed.

Troubleshooting

The i-STAT System is designed to measure fresh whole blood samples. Matrix effects and interfering substances can be expected when measuring non-whole blood samples. The following points should be considered when selecting and testing external quality control samples:

- Aqueous samples intended to assess blood gases will not be measured by the i-STAT System unless electrolytes, or at least sodium, are present.
- Fluorocarbon samples are not compatible.
- Preserved-cell samples, other than Meter Trax (Hematronix, Inc) whole blood controls for glucose and hematocrit, are not compatible. (The i-STAT System will report only hematocrit for Meter Trax controls.)
- Aged serum and lyophilized serum may contain degradation products or preservatives that interfere with the measurements.
- Matrix effects between aqueous-based and protein-based samples may cause results from the i-STAT System to differ from reference methods or other comparative methods.
- Aqueous samples that contain a resistive substance to allow assessment of conductometric hematocrit measurements will cause the i-STAT System to extrapolate ambient temperature results to 37 °C results for pH and $P\text{CO}_2$ as if the sample were whole blood. Since extrapolation coefficients for aqueous and whole blood samples differ, results on the i-STAT System for these samples may not agree with other methods.

While the various cartridges give the same results for whole blood samples, there may be small differences between generations and types of cartridges for non-whole blood samples. Generation means major manufacturing changes such as making the chips smaller. Cartridge types means those that make measurements at ambient temperature and those that make measurements at 37 °C.

Administrative errors include choosing the wrong method or peer group and transcription errors.

Procedure for Test Strips

Display	Action	Analyzer Response
	Press the **On/Off** key	Logo briefly displayed followed by Test Menu.
Test Menu	Press the **Menu** key	
Administration Menu	Press **3** for Quality Tests	
Quality Tests 1 – Control 2 – Proficiency 3 – Cal Ver 4 - Simulator	Press **2** for Proficiency	
Quality Tests Proficiency 1 – i-STAT Cartridge 2 – PCx Glucose Strip	Press **2** for PCx Glucose Strip	
Scan or Enter Operator ID.	Press **Scan** to scan the Operator ID or manually enter using the keypad and press **Enter**.	In enabled, the analyzer will validate the ID. If enabled, the analyzer will prompt for the ID to be repeated.
Scan or Enter Proficiency ID	Press **Scan** to scan the Proficiency ID or manually enter the characters that identify the sample and press **Enter**.	An ID of up to 15 characters can be entered.
Scan or Enter Strip Lot Number	Press **Scan** to scan the Strip Lot Number or manually enter the Strip Lot Number using the keypad and press **Enter**.	Possible messages: "Lot Expired", "Invalid Number", "Invalid Length", "Strip Lot xxx Is Not in List"
Select Sample Type: 1 – Arterial or Capillary 2 - Venous	Press **1** or ***2*** to select the correct sample type.	For consistency across sites, select: 1-Arterial or Capillary.
INSERT STRIP	Open the foil test strip packet at the notch and tear up or down to remove the test strip. With the contact bars facing up, insert the test strip into the test strip port until it stops.	
Apply Proficiency Sample	Follow the directions for use for the sample. Apply a drop of sample directly from the bottle or transfer device to the target area on the test strip.	The monitor beeps when the sample is accepted The test starts automatically as the sample is accepted.

Procedure for Test Strips (continued)

Display	Action	Analyzer Response
Precision PCx Blood Glucose Strip Time to Results → Page	Enter Chart page information if desired.	The analyzer counts down 20 seconds, then displays the test result. If the → key is pressed, the Chart page will be displayed. The sample type will be displayed along with 3 free fields in which comments of 9 characters each can be entered. The analyzer may be customized to present the Chart page automatically.
Results 1 – Test Options	Remove the strip from the analyzer when finished testing. Test Options Proficiency 1 - New Sample 2 - Same Sample 3 - History	If Action Ranges are enabled, an up (high) or down (low) arrow will be displayed with the result. If Comment Code is enabled, the analyzer will request the operator to Scan or Enter Comment Code. Up to 3 characters can be entered.

ROUTINE CARE of the ANALYZER and DOWNLOADER 17

Drying a Wet Analyzer or Downloader

If the analyzer is placed on a wet surface or if any liquid is spilled onto it, dry the analyzer immediately. If liquid enters the following compartments, the analyzer may be damaged:

- The electronics compartment
- The battery compartment
- The cartridge port
- The test strip port

The Downloader may also be damaged by liquid contamination. Unplug the power supply from the outlet and dry the Downloader completely.

Cleaning the Analyzer and Downloader

Clean the display screen and the case using a gauze pad moistened with any of the following:

- A mild non-abrasive cleaner
- Detergent
- Soap and water
- Alcohol
- 10% bleach solution
- PDI® Super Sani-Cloth® (solution of IPA, n-Alkyl dimethyl ethylbenzyl- and benzyl- ammonium chloride)

Rinse the case using another gauze pad moistened with water and dry. Avoid getting excess fluids in the seam between the display screen and the case.

(PDI and Sani-Cloth are registered trademarks of Sani-System™ Brand Products, the Health Care Division of Nice-Pak Products, Orangeburg, NY, USA.)

Caution

Exercise universal safety precautions at all times when handling the analyzer, cartridges, and peripherals to prevent exposure to blood-born pathogens.

The analyzer is NOT designed to be sterilized or autoclaved by any method, including those using gas (e.g. steam, ethylene oxide, ect...) high heat, bead, radiation, or other chemical processes. The analyzer is splash resistant, but should not be immersed in any liquids.

Dispose of analyzer, peripheral electronics, and batteries according to local, state, and/or national guidelines.

If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage.

Decontaminate the analyzer or Downloader whenever a specimen is spilled onto it or if the item is to be returned to i-STAT for repair. Wear gloves while performing the following procedure.

Procedure

STEP	ACTION
1	Prepare a 1:10 solution of household bleach by mixing one part of bleach with nine parts of tap water. This solution will maintain its germicidal action for a week.
2	Soak a few gauze pads in the bleach solution. Before use, squeeze the pads to remove excess solution.
3	Soften, then remove any dried blood with one or two of the gauze pads soaked in the bleach solution. Avoid scraping dried blood as contaminated particles may become airborne.
4	Clean the entire surface of the device twice with gauze pads soaked in the bleach solution.
5	Rinse the surface of the device with gauze pads moistened with tap water and dry.
6	If the device is to be shipped, place it in a plastic bag.

Removing and Replacing Disposable Batteries

Wait until any test in progress is completed, and turn off the analyzer before replacing the batteries or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the battery carrier which contains the two 9-volt batteries.
3	Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
4	Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient the new battery so it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the battery inward. The terminals of the battery should be underneath the protective bar on the carrier. Repeat for the second battery on the other side of the carrier.
5	Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the instrument first. Insert the carrier into the instrument as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.
6	Slide the battery compartment door back into place.

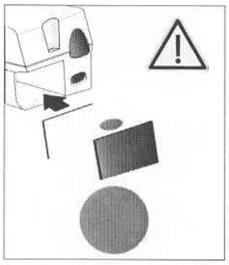
Caution

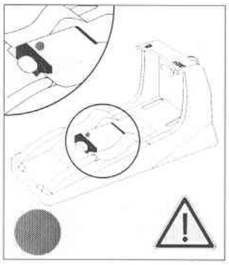
A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

Removing and Replacing the Rechargeable Battery

Wait until any test in progress is completed, and turn off the analyzer before replacing the battery or the most recent set of results may be lost. Stored results will not be lost when replacing the batteries.

STEP	ACTION
1	Slide the battery compartment door off.
2	Tilt the analyzer slightly to slide out the rechargeable battery pack.
3	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the pack into the analyzer as shown on the label. If the pack is inserted incorrectly, the battery door will not close.
4	Slide the battery compartment door back into place.





UPDATING THE SOFTWARE 18

CLEW

The i-STAT System is designed to eliminate operator influence on delivered results. Unlike other unit-use systems, the user is not required to enter lot-specific calibration information into the instrument. The micro-fabricated sensor technology produces very repeatable devices from lot to lot which allow the Analyzers to use the same set of standardizing values for extended periods of time.

Nevertheless, the continuous manufacturing process improvements by i-STAT necessitate re-establishing standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. New CLEW re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

Application Software

The "Application" software, listed under Version on the Analyzer Status page, is updated to enable the analyzer to recognize new cartridges and to enable new features. These updates typically occur at the same time as the CLEW updates.

Software Updates

Software update packages are mailed to each site two times a year and approximately two months before the current CLEW expires. The package includes a diskette with new versions of CLEW or both CLEW and application software, a Product Update explaining any changes, directions for updating software, and new Value Assignment Sheets for control solutions. The procedure for updating software includes transferring the new software from the diskette to the Point-of-Care Central Workstation, updating one or a few analyzers from the Workstation, and updating other analyzers around the facility from the ones updated at the Workstation. A PC with Windows 95 or higher can be used in place of the Point-of-Care Central Workstation. Note: The COM ports of certain laptops may need to be reconfigured to communicate with the Downloader. If communication cannot be established, a standard PC should be used.

UPDATING ANALYZER SOFTWARE: JAMMLITE UTILITY

The JammLite Utility must be used to update software in the i-STAT®1 Analyzer and can be used to update the i-STAT Portable Clinical Analyzer and the Blood Analysis Module. The JammLite procedure is simple with just one screen for all analyzer types and software versions.

To use this utility, you must have a computer with Windows® 95 or higher. An i-STAT Central Data Station Version 5 or a Point of Care Central Workstation meet this requirement and can be used. An i-STAT/DE server is not recommended for use with this utility.

If this is the first time you are updating your analyzer, follow the Detailed Procedure. If you just need reminders, follow the Summary of the Procedure.

SUMMARY OF THE JAMMLITE PROCEDURE

How to	Step	Page
Check battery voltage Save the data on Portable Clinical Analyzers	1	18-3
Disable Customization on the Central Data Station	2	18-3
Shut down all programs on the computer	3	18-3
Connect an IR Link or Downloader* to the computer	4	18-4
Access the C:\> prompt	5	18-5
Transfer the files from the JAMS disk to the computer	6	18-5
Access the JammLite Utility	7	18-6
Select the instrument (analyzer) type to be updated	7	18-6
Select the local port or select TCP\IP and enter the IP address	7	18-6
Select the Application software and CLEW	7	18-6
Click on Update and follow the directions on the screen	7	18-6
DO NOT move analyzer during update	7	18-7
Click on Close	7	18-7
Click on Exit or X in upper right corner of screen	7	18-7
Re-start the CDS, update CLEW, re-eanable Customization	8	18-7
Insert an Electronic Simulator into each updated analyzer	9	18-7

* It is not neccessary to connect a serial Downloader if using network protocol to update i-STAT 1 Analyzer.

DETAILED JAMMLITE PROCEDURE

Step **Action**

Step (1)

Save Stored Results & Check Battery Voltage

Save Data: All test records are erased in the i-STAT Portable Clinical Analyzer (series 200) when the application software is updated. Download each analyzer to the Central Data Station (CDS) program or ensure that all test records have been transcribed before updating a Portable Clinical Analyzer. Test records are not erased from the i-STAT1 Analyzer (series 300).

- There are two types of software in the analyzers: application (JAMS) and CLEW.
- The Product Update lists the software that is to be updated.
- Test records will not be erased if only the CLEW software is updated.

Check Battery Voltage: Analyzers consume power during the software update. For the software update, the battery voltage should be well above the 7.5 V point at which the low battery message is displayed.

Step (2)

Disable Customization on CDS

If you do not use Customization or Customization is disabled, skip this step. If you use Central Data Station Version 5 and your CDS is on Version 5.18a or higher, skip this step.

If you are not sure if Customization is disabled, follow the steps below. The steps to disable customization differ for the Central Data Station Version 4 and Central Data Station Version 5. If you are not sure which CDS you have, click **Help** on the main menu bar, then click on **About....**

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on File on the menu bar.
4. Click on Disable Customization.
5. Click Yes to the confirmation messages and the Utility will close.

Central Data Station Version 5:

1. Click on Administration in the main menu bar.
2. Click on Customization.
3. Type in the Password. The default password is istat.
4. Click off the checkmark in the box beside Enable Customization at the top left of the window.

Step (3)

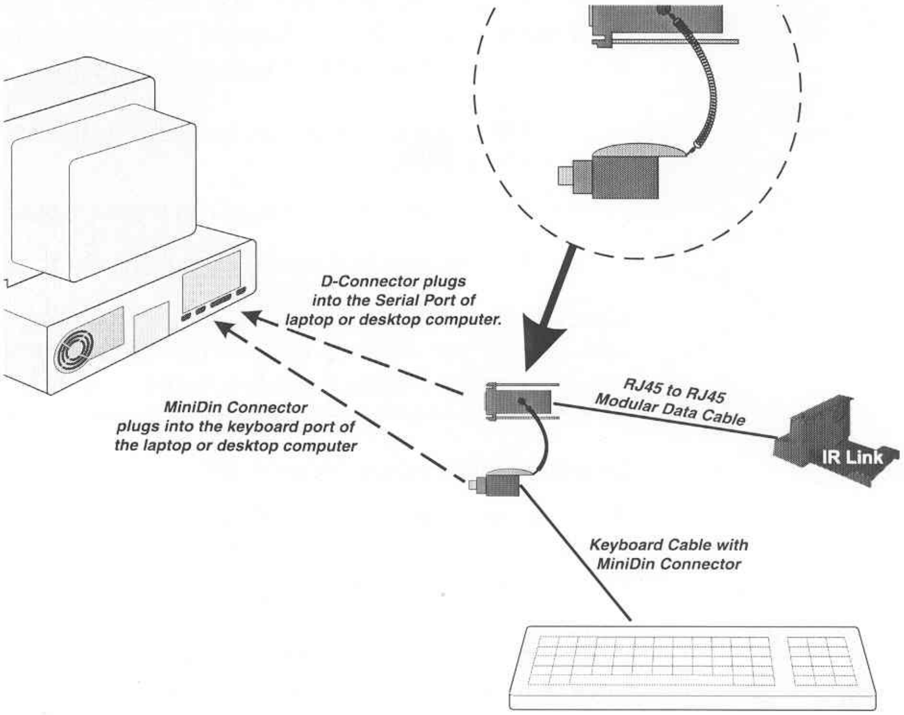
Shut Down All Programs

Exit the CDS and all other open programs.

Step (4) *Connect the IR Link and/or Downloader*

IR Link connection:

- If using a Central Data Station Version 5, a Central Data Station Version 4 with digiboard, or any other computer using Windows 95 or above, connect the IR Link to a 9 pin COM port using an i-STAT Software Update Kit as illustrated below.


D-Connector plugs into the Serial Port of laptop or desktop computer.
MiniDin Connector plugs into the keyboard port of the laptop or desktop computer
RJ45 to RJ45 Modular Data Cable
IR Link
Keyboard Cable with MiniDin Connector

- If using a Central Data Station Version 4 with quad cards: Connect the IR Link to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors). COM5 is first port from the inside on the lower row.

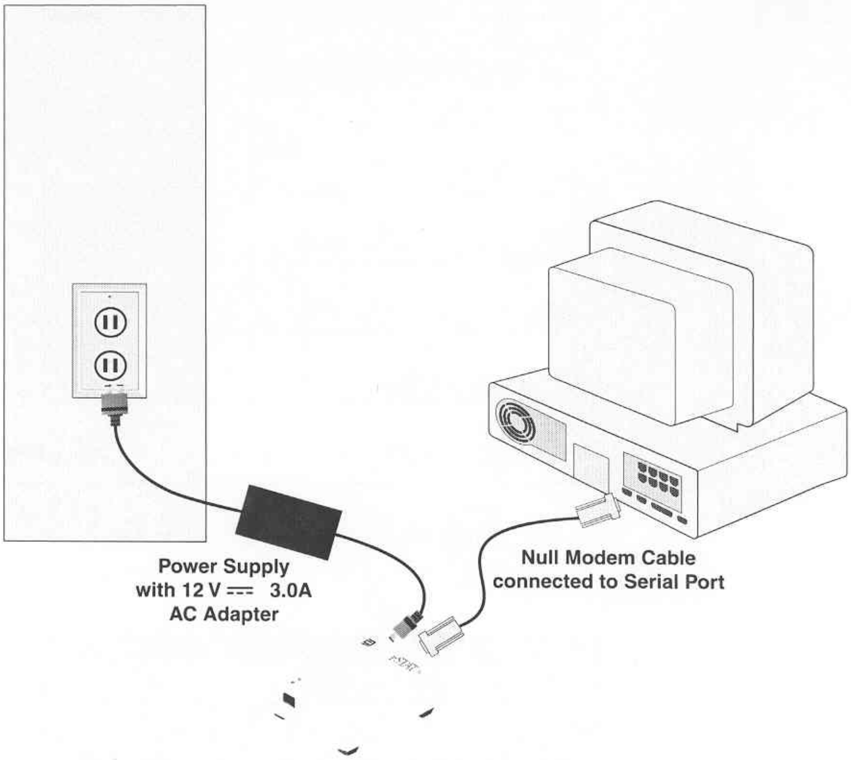
Blood Analysis Module connection:

- If using a Central Data Station Version 4, connect the BAM to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors).
- If using a Central Data Station Version 5 or another computer, connect the BAM to a 9 pin COM port using the D-Connector and Mini Din Connector from an i-STAT Software Update Kit.

Note: Do not connect the BAM until instructed to do so by the JammLite program.

Serial Downloader connection:

- Connect a serial Downloader to a COM port using a DB9-DB9 Null Modem cable and plug the Downloader's power adapter into a wall outlet.



Network Downloader connection:

- Connect a network Downloader to the network using a network patch cable and plug the Downloader's power adapter into a wall outlet. The computer must also be connected to the network. The computer must support the TCP/IP network protocol.

Step (5)

Access the Command Prompt

- Click Start in the lower left corner of the window.
- Click Run.
- Type: **command** and press the Enter key.

Note: If you do not have access to the **Run** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

Step (6)

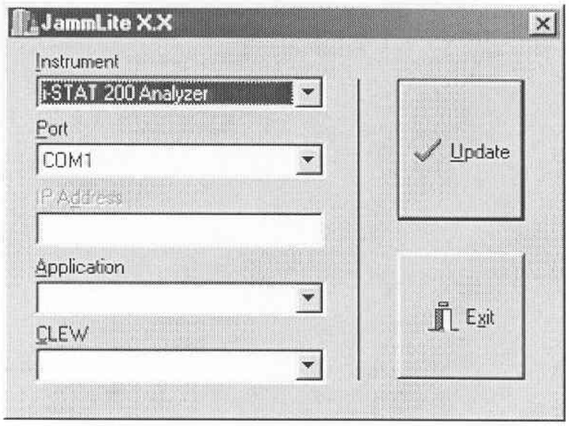
Transfer the Files

Place the JAMS diskette into the A:drive. At the Command prompt, type **A:transfer** and press the Enter key.

Step (7)

Using the JammLite Utility

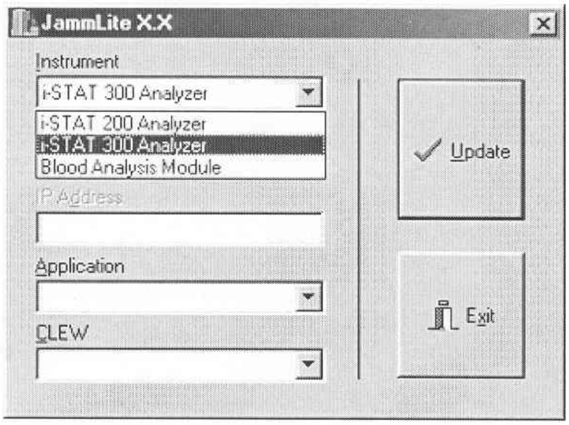
1. At the C:\>bins prompt, type **jammlite** and press the Enter key. The following screen will be displayed with the new application and CLEW.


JammLite X.X
IP Address
Application
CLEW
Update
Exit

Instrument: i-STAT 200 Analyzer
Port: COM1

X.X is the current version of JammLite software.

2. Select the appropriate instrument from the Instrument drop-down list.


JammLite X.X
i-STAT 200 Analyzer
i-STAT 300 Analyzer
Blood Analysis Module
IP Address
Application
CLEW
Update
Exit

Instrument: i-STAT 300 Analyzer

Note: i-STAT 200 Analyzer is the Portable Clinical Analyzer and the i-STAT 300 Analyzer is the i-STAT 1 Analyzer.

3. Select the port for the instrument being updated from the "Port" drop-down list. The JammLite program will list only available ports on the computer. For updates using a network Downloader, select TCP/IP. (The TCP/IP option is available only if i-STAT 300 is selected from the "Instrument" drop down list.) Enter the IP address of the Downloader in the "IP Address" box.

4. Select the appropriate Application and CLEW from the Application and CLEW drop-down lists. Refer to the update package for the correct Application and CLEW. If the update is for CLEW only, select None for Application. Note that there are different application versions for the i-STAT 1 Analyzer, the Portable Clinical Analyzer and the Blood Analysis Module. JammLite will display all application software and CLEW appropriate for the selected instrument.

5. Click on the Update button to start the update. Appropriate instructions will be displayed. Follow the directions on the screen. The selected application and CLEW will be displayed on the Update Line.

6. During the update, do not move the analyzer or unplug the Blood Analysis Module until a screen is displayed indicating the update was successful.
7. Click on Close. The JammLite program will return to step 7 to allow any selections to be changed before starting another update.
8. When all analyzers have been updated, click on Exit or the X in the upper right corner of the DOS window.

Step (8)

Restarting the Central Data Station

If using a Central Data Station, re-start the software, update the Customization Profile(s) with the new CLEW and enable Customization if desired.

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on Setup Mode.
4. Click on NEXT for the Language window.
5. Click on the new CLEW in the CLEW window and click on NEXT.
6. Click on NEXT in the Unit Set window.
7. Click on FINISH in the Preference window.
8. Click on FILE and Exit Program or click on the x in the upper right corner of the Utility window.
9. Click on the Central Data Station icon.

Central Data Station Version 5:

1. Click on the Central Data Station icon.
2. Click on Administration.
3. Click on Customization.
4. Type in the Password. The default password is istat.
5. Click the i-STAT Analyzer CLEW button.
6. Click the new version of CLEW and click OK.
7. If "Use Default Profile" is not check-marked beside any localization-based customization profiles, double click the box with the CLEW under the i-STAT Analyzer column (or Agilent BAM CLEW) and click the new version of CLEW.
8. Click a checkmark in the box beside Enable Customization at the top left of the window.
9. Click the x in the upper right corner of the Customization window to close it.

Step (9)

Verifying the Update

Run an external Electronic Simulator on updated analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

PROBLEM	RECOMMENDED ACTION
The Com port to be used for the update is not listed in the Port List	Exit the JammLite program and ensure that there are no other programs running which may be using the port (such as the Central Data Station). Restart the JammLite program to determine if the port is now listed.
A message appears on the screen that the port specified for the update could not be opened.	Verify that no other programs are using the port and that the correct port was selected.
A message appears on the screen that the specified application file could not be opened, has an error, or is not a valid application file.	Verify that all other programs are closed and that the proper application was selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the application update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that there was an error encountered during communication with the analyzer.	Ensure that the instrument is located properly in the IR Link or Downloader, and this it is not removed before the update is completed.
A message appears on the screen that the specified CLEW file could not be opened, has an error, or is not a valid CLEW file.	Ensure that all other programs are closed and that the correct CLEW is selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the CLEW update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that the Downloader could not be configured to perform the update	Verify that the Downloader is connected to the COM port, the Downloader is powered, and that the proper port is selected.
A message appears on the screen indicating that nothing was selected for the update.	Select an Application and/or a CLEW prior to clicking on the Update button.

Quality Check Code 13 - Invalid or Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Update CLEW in the customization profile(s) and download the analyzers. The new CLEW will be installed in the analyzers.

Unsuccessful with Windows 95

Some computers with Windows 95 will not run JammLite. In this case, Jammit must be used to update analyzers. Before accessing the Jammit Utility, the computer must be rebooted.

ANALYZER-TO-ANALYZER SOFTWARE UPDATES

i-STAT 1 Analyzer

Step	Action
1	Any updated analyzer can be used as the sending analyzer. Select the Utility option under the Administration Menu on the sending analyzer. The Utility menu can be password protected. Enter the password or press the Enter key if no password has been specified. From the Utility Menu select **1-Send Software**. Select **1 – JAMS and CLEW** or **2-CLEW** as required for the update. The message "Waiting to Send" will be displayed.
2	Ensure that the receiving analyzer is off.
3	Place the sending and receiving analyzers facing each other on a flat surface about 30cm (1 foot) apart and align their IR windows. Move one analyzer toward the other until the message "Sending…" is displayed on the sending analyzer and a scrolling banner appears on the receiving analyzer.
4	Do not move the analyzers until the "Sending…" message is removed from the sending analyzer's display. The sending analyzer will return to the Send Software option and will display the result of the last software update as "Successful" or "Unsuccessful."
5	Select the Analyzer Status option under the Administration menu on the receiving analyzer and check that the new JAMS and/or CLEW are listed.

Step	Action
1	Any updated analyzer can be used as the Sending Analyzer. Run the external Electronic Simulator on the Sending Analyzer.
2	Transmit all data from the analyzer being updated (the Receiving Analyzer) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.
3	With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.
4	In the Utility Menu, select 3 - Send Software. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".
5	Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-1 of the i-STAT System Manual for the location of the IR LED.)
6	On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the DIS key. The Sending Analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed. Note: Do not move the analyzers while the software is being sent.
7	When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. Do not press the DIS key on the Receiving Analyzer. Run the Electronic Simulator on the Receiving Analyzer.
8	To update software in another analyzer, repeat these instructions from Step 2.

PERFORMING A JAMS AND CLEW UPDATE ON AN i-STAT 1 ANALYZER USING THE CUSTOMIZATION WORKSPACE

1. *Transfer the Files*

   - Place the JAMS diskette into the A: drive.
   - Click **Start** ⇨ **Run...**
   - Type: **a:transfer** and press the **Enter** key.

Note: If you do not have access to the **Run...** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

2. *Start the Central Data Station Application (if not already open)*

   - Click on the Central Data Station icon.

3. ***Access the Customization Workspace***

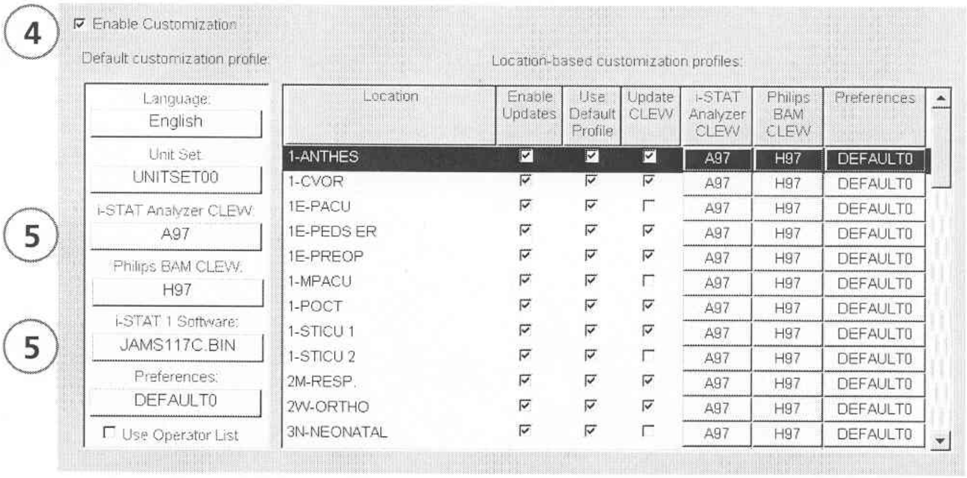
   - Click on **Main** ⇨ **Open Administration Function** ⇨ **Customization**
   - Type in the Password. The default password is **istat**.

4. ***Enable Customization***

   - If the Enable Customization box is not already checked, click the box next to this listing.
   - Under the "Location-based customization profile:" section, make sure Enable Updates is checked for every location from which you wish to perform software updates on your i-STAT 1 Analyzers.

5. ***Select the Desired Analyzer CLEW and i-STAT 1 Software***

   - Under the "Default customization profile:" column, click on the i-STAT Analyzer CLEW button. Click the new version of CLEW and click OK.
   - Under the "Default Customization profile:" column, click on the i-STAT 1 Software button. Click the new i-STAT 1 software file and click OK.



☑ Enable Customization

Default customization profile:

Language: English

Unit Set: UNITSET00

i-STAT Analyzer CLEW: A97

Philips BAM CLEW: H97

i-STAT 1 Software: JAMS117C.BIN

Preferences: DEFAULT0

☐ Use Operator List

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences
1-ANTHES	☑	☑	☑	A97	H97	DEFAULT0
1-CVOR	☑	☑	☑	A97	H97	DEFAULT0
1E-PACU	☑	☑	☐	A97	H97	DEFAULT0
1E-PEDS ER	☑	☑	☑	A97	H97	DEFAULT0
1E-PREOP	☑	☑	☑	A97	H97	DEFAULT0
1-MPACU	☑	☑	☐	A97	H97	DEFAULT0
1-POCT	☑	☑	☑	A97	H97	DEFAULT0
1-STICU 1	☑	☑	☑	A97	H97	DEFAULT0
1-STICU 2	☑	☑	☐	A97	H97	DEFAULT0
2M-RESP.	☑	☑	☑	A97	H97	DEFAULT0
2W-ORTHO	☑	☑	☑	A97	H97	DEFAULT0
3N-NEONATAL	☑	☑	☐	A97	H97	DEFAULT0

6. ***Update the Software in the i-STAT 1 Analyzer***

   - Go to the location where the i-STAT 1 Analyzers you wish to update are located.
   - Press the On/Off button on the analyzer to turn the display on.
   - Press the Menu key to bring up the Administration Menu.
   - Press 7 for Utility. The Utility menu may be password protected. Enter the password or press the Enter key if no password has been specified.
   - From the Utility Menu, select **3-Receive Software**. The "Waiting to Send" message will appear on the analyzer display.
   - Place the analyzer in the downloader or downloader/recharger. A Communication in Progress message will appear on the screen. After this message disappears, the analyzer display will stay blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the procedure.

- A scrolling bar will then appear on the analyzer display. This bar indicates that the software is uploading into the analyzer. Do not move the analyzer while the scrolling bar appears on the display screen. When the upload process is complete, the scrolling bar will disappear and the analyzer display will again go blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the process.
- A Waiting to Send message followed by a Communication in Progress message will then appear on the analyzer display. After these messages disappear, the analyzer display will go blank, and the update process is complete.

7. ***Verify the Update***

    - Run an external Electronic Simulator on updated Analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

TROUBLESHOOTING THE ANALYZER 19

Introduction

When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem and the next step to be taken will be displayed. The Code number may be helpful to a technical support representative if a problem cannot be resolved. If a problem cannot be resolved by the procedures described in this section, refer to Support Services information in the Troubleshooting section.

Note: Troubleshooting for results and quality tests are covered in those sections of this manual.

Note: The Technical Bulletin "Analyzer Coded Messages" included in this manual lists the Quality Check Code numbers as well as additional troubleshooting details

Caution

DO NOT OPEN THE ANALYZER, or any other i-STAT product, or perform any unauthorized procedures. Opening any i-STAT product, including analyzer, Electronic Simulator, printer or communication device, in attempt to repair it or resolve a problem may cause erroneous results. If the troubleshooting procedures found in this manual or requested by an i-STAT support specialist do not resolve the problem, the product must be returned to i-STAT for repair.

Information Needed

Have the following pertinent information available for review with the representative:

- Description of problem
- When problem first occurred and what has been done so far to resolve the problem
- Serial number of component(s)
- Displayed message and code number
- Frequency of problem
- Software version
- Environmental conditions
- Result of last Electronic Simulator test
- Battery voltage from Analyzer Status page

STARTUP MESSAGES

Overview

Whenever the analyzer is turned on using the On/Off key, the analyzer performs self-checks. If a condition that should be corrected in the near future, but that will not affect results is detected, a warning is displayed. The operator presses the 1 key to continue with testing. If the analyzer has been customized to disable testing under any of these conditions, the condition must be corrected and the analyzer turned off and back on before testing will be enabled.

Message on Display	Explanation	How to Respond
Electronic Simulator Test Required	Analyzer customized to alert the operator that a scheduled simulator test is due.	Insert the external Electronic Simulator at the earliest convenient time.
PCx Glucose Strip Control Required	Analyzer customized to alert the operator that scheduled control tests are due.	Test the controls at the earliest convenient time.
Stored Memory Low	Memory space for 50 unsent test records available before the "Stored Memory Full" message is displayed.	Place the analyzer in a Downloader.
Stored Memory Full	The analyzer is customized to alert the operator that the memory for unsent records is full. If the operator does not transmit the test records to the Point-of-Care Central Workstation, the analyzer will either block further testing or will overwrite oldest records depending on how the analyzer is customized.	Place the analyzer in a Downloader.
Upload Required	The analyzer is customized to alert the operator that a scheduled transmission of test records to the Central Data Station is due.	Place the analyzer in a Downloader.
Battery Low	Battery voltage has dropped to 7.4 volts. There is sufficient power to test a few more cartridges and strips, the number depending mainly on the types of cartridges in use. Under this condition, a flashing battery icon will also appear on the result page.	Change the disposable lithium batteries or recharge the rechargeable battery.
CLEW Expiring, Update Required	Message appears 15 days before the software expires.	Update the analyzer before the expiration date.

TEST CYCLE MESSAGES AND QUALITY CHECK CODES

Overview

If a problem is detected during a testing cycle, the cycle will be stopped and a message will identify the problem and indicate the next step to be taken. If the problem causes testing to be disabled, the problem must be corrected and the analyzer must be turned off and back on before testing will be enabled.

Environmental Conditions

The following messages usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the the offending condition is corrected.

Message on Display	Cause	Action
Date Invalid, Check Clock	The analyzer will not allow a date that precedes or exceeds the six months lifetime of the CLEW software.	Press **Menu** once to go to the Test Menu and then again to go to the Administration Menu. Press 5 to go to the Set Clock screen and correct the date.
Dead Batteries, Replace Batteries	There is insufficient battery power to complete a test cycle.	Change the disposable lithium batteries or recharge the rechargeable battery.
Temperature Out of Range, Check Status Page	The analyzer makes a temperature measurement before initiating a test cycle.	Check the temperature reading on the Analyzer Status screen (under the Administration Menu). If below the operating range, move to a warmer area. If above the operating range, move to a cooler area. Allow time for the analyzer to equilibrate to the new temperature. Check the Analyzer Status screen periodically.
Invalid or Expired CLEW	The software has become corrupt or has expired. The Product Update for each software update includes the expiration date.	Verify that the date in the analyzer is correct. Change the software if expired. Update the software again if not expired. If the message is displayed again, refer to Support Services information at the end of this section.
Analyzer Interrupted, Use Another Cartridge	The analyzer detected that the last cartridge run was not completed. This can happen if battery voltage is low, or if batteries were removed or making poor contact while a cartridge was still in the analyzer.	Check that the battery pack is inserted properly. Turn the analyzer on and check for the Low Battery message; replace or recharge if needed.

Error in Cartridge or Fluid Movement

The following conditions usually indicate an error condition relating in some way to the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may be an analyzer problem.

Message on Display	Cause	Action
Cartridge Error Use Another Cartridge	These codes can all be caused by a variety of reasons including sample-related problems, users, cartridges or analyzers. Single or sporadic errors are most likely a sample-related problem (an interferent), an aberrant cartridge, or a user-induced situation such as touching cartridge contacts, pressing on center of cartridge or bubbles in the sample ("frothy" samples).	Use another cartridge. If the same code repeats more than twice, there may be an analyzer problem. Try another analyzer if available.
Cartridge Preburst Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: • Cartridges may have been frozen. • Calibrant pack may have been burst by operator exerting too much pressure on the center of the cartridge.	Try another cartridge. Make sure that the cartridges were not frozen.
Unable to Position Sample Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to: • not closing the snap closure on the cartridge. • a clot in the sample preventing movement of the sample. • an aberrant cartridge.	Use another cartridge.
Sample Positioned Short of Fill Mark Use Another Cartridge	The cartridge was under-filled.	The sample must reach the fill mark. Try another cartridge.
Sample Positioned Beyond Fill Mark Use Another Cartridge	The cartridge was overfilled.	The sample was past the fill mark. Try another cartridge.

Error in Cartridge or Fluid Movement (continued)

Message on Display	Cause	Action
Insufficient Sample Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample.	Try another cartridge.
Cartridge Not Inserted Properly Reinsert Cartridge	The code indicates the cartridge or external Electronic Simulator may not be pushed in all the way.	Reinsert the cartridge or Electronic Simulator. If problem is recurrent and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an instrument problem. Refer to Support Services.
Test Cancelled by Operator	No response to mandatory prompt before analyzer time out.	No action required. Training may be required if a particular operator has a high rate of cancelled tests.

Electrical or Mechanical Failures

The following conditions are related to electronic or mechanical failures in the analyzer.

Message on Display	Cause	Action
Analyzer Error Use Electronic Simulator	The analyzer usually recovers from these errors when the Electronic Simulator is run. This error can occur if the cartridge or Electronic Simulator was "angled" when inserted.	Push cartridge or Simulator straight through the cartridge port. This error can also occur if the Electronic Simulator is malfunctioning (has it been dropped?). Try another Simulator. If the analyzer passes the Electronic Simulator check, continue to use it. If not, or if the Quality Check Code is recurrent, the analyzer may need repair.
Analyzer Error See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover.	Use an external Electronic Simulator twice and use a cartridge with sample or control solution. If an error condition occurs, refer to Support Services. If not, continue to use the analyzer.
Cartridge Type Not Recognized Use Another Cartridge	This error could be due to use of a cartridge type that is not compatible with the version of software in the analyzer.	If this is a new cartridge type being used, update the software. If the cartridge type has been used before, check to see if the cartridges have expired. Otherwise, an analyzer problem is indicated and the analyzer may need repair.

Glucose Strip Errors

Message on Display	Cause	Action
Strip Error Use Another Strip Code 100	The test strip or the test port is wet, defective, contaminated, or the wrong test strip was inserted.	Remove the test strip. Press **1** for Test Options. Press **1** for Same Patient or Level. Repeat the test.
Strip Error Use Another Strip Code 101	The test strip was removed from the test port during testing.	Press **1** for Test Options. Press **1** for Same Patient or Level. Repeat the test.
Strip Error Use Another Strip Codes 103, 105, 106, 107	Test unsucessful. An error was detected during the analysis sequence.	Remove the test strip. Press **1** for Test Options. Press **1** for Same Patient or Level. Repeat the test. If the problem persists, record the three digit error code and contact Support Services.
Strip Error Use Another Strip Codes 102, 104	The test strip malfunctioned or the blood glucose level is beyond the measuring capability of the test strip and strip reader.	Remove used test strip. Press **1** for Test Options. Press **1** for Same Patient or Level. Repeat the test with a new test strip. If the error occurs again, confirm the result by performing the test by a different method. Contact Support Services.
Temperature Out of Range Check Status Page Codes 108, 109	During the test, room temperature became unstable or moved outside the limits within which the test strip reader can perform a test.	Ensure that the room temperature is within the secified limits. Allow the analyzer to stabilize to room temperature: 15 to 40 °C or 59 to 104 °F . Press the Menu key until the Administation Menu is displayed. Press **1** for Analyzer Status where the room temperture reading is displayed.

No Display

Symptom	Possible Cause	Action
The display screen remains blank, either after a cartridge has been properly inserted or after the On/Off key has been pressed.	Batteries dead. Keypad not responding. Internal Start switch broken.	Change or recharge batteries. If this does not fix the problem, reinstall the current software in the analyzer. If the problem persists, the analyzer should be returned for repair.

"Cartridge Locked" Not Removed

Symptom	Possible Cause	Action
Normally the analyzer will reset and release the cartridge after the testing cycle is completed. If the analyzer cannot reset, the "Cartridge Locked" message will remain on the screen.	Dead batteries. Mechanical problem.	Wait until the analyzer turns off or turn the analyzer off. Then turn the analyzer on. If it can reset, it will release the cartridge and remove the "Cartridge Locked" message. If the cartridge is not released, change or recharge the battery and turn the analyzer on. If the "Cartridge Locked" message does not disappear, do not attempt to remove the cartridge and refer to Support Services.

THEORY 20

ANALYZER FUNCTIONS

Introduction

The i-STAT 1 analyzer is a microprocessor-controlled electromechanical instrument designed to:

- identify the cartridge type.
- control the flow of fluids within the cartridges.
- mix sample and reagent (where applicable).
- apply electrical signals to certain types of sensors within the cartridges.
- control the temperature of the cartridge at 37°C (where applicable).
- measure electrical signals generated by the sensors (cartridge and test strip).
- measure the barometric pressure of the surrounding environment (where applicable).
- calculate concentrations of analytes using the generated electrical signals.
- display the results in numerical values and on bar graphs (where applicable).
- communicate the results to a printer and computer.
- sense and communicate operational errors.
- maintain an internal clock/calendar.
- store all test records, Electronic Simulator results and Quality Check Codes and messages.

Microprocessor System

The microprocessor control system manages all functions of the analyzer. It accesses three types of memory storage devices. A "FLASH" EEPROM module stores the software program in the analyzer. The RAM, which is backed up by an internal lithium battery, is used for temporary storage of sensor signals measured during operation and for storage of test records. Another EEPROM stores factory calibration information, the instrument serial number and cumulative count of uses. Neither of the EEPROMs relies on the lithium battery for maintaining information.

Sensor Interface

Electrical signals from the cartridge sensors are conducted from the contact pads on the cartridge, through the internal connector in the analyzer, to the sensor interface circuit board. Electrical signals from the test strip sensor are conducted from the contact bars to a sensor interface circuit board. These circuits amplify the signals from the sensors so that they can be further processed by the main electronic circuit board. Four signals are relayed to the main electronic circuit board from the cartridge sensor interface circuit board:

- A multiplexed potentiometric signal line
- A multiplexed amperometric signal line
- An AC fluid conductivity signal
- A digital identification code to identify the type of cartridge being inserted into the analyzer

Mechanical System

A single DC gearmotor drives mechanical system components:

- An electrical interconnecting system which brings the analyzer's electrical internal connector into contact with the contact pads on the cartridge
- A calibrant delivery system
- A sample delivery system
- A thermal control interconnectivity system which brings the analyzer's thermal controller into contact with heater elements on the back of cartridges. In addition, a latching mechanism locks the cartridge into place upon insertion.

Analog-to-Digital Conversion

An analog-to-digital converter converts all analog signals into digital form so that the microprocessor can perform mathematical calculations on the signals. An analog signal multiplexer makes it possible for the microprocessor to measure eight different types of analog signals:

- The potentiometric signals from the sensor interface circuit
- The amperometric signals from the cartridge and test strip sensor interface circuits
- A DC conductivity signal
- The battery voltage
- A thermistor signal representing the internal temperature of the analyzer
- A motor feedback signal used to control the speed of the mechanical motion
- Cartridge temperature signals used to control the cartridge temperature to 37°C
- A pressure transducer signal representing the barometric pressure of the environment

Analog Control Signals

The analyzer creates and applies two types of signals to the sensors: a digital-to-analog converter generates a voltage which is applied to amperometric sensors, and the AC conductivity circuit generates an AC excitation signal which is applied to the conductivity sensors. The digital-to-analog converter also provides voltages to the motor driver circuit.

Operator Interface

The microprocessor control system coordinates the reading of information input by the user, the writing of information onto the display, and the communication of results. The microprocessor control system, also, communicates with a clock/calendar circuit allowing the operator to set and read the time and date. The clock/calendar circuit is backed up by a lithium battery.

ELECTROCHEMICAL MEASUREMENTS

Method

Measurements are performed on undiluted specimens. Undiluted methods are also called direct methods, while methods requiring dilution of the sample are called indirect methods.

Indirect methods measure the total molar concentration of analyte per unit volume of plasma. Direct methods measure the total molar activity of analyte (apparent or free ion activity) per unit volume of plasma water. It is understood that the direct method result is the clinically significant result for electrolytes. When there is disagreement between the methods, such as when the patient has abnormal total protein or lipid levels, it is due to interference on the indirect method.

At normal levels of protein and lipids the systematic offset between methods is often corrected for in commercial direct measuring instruments so that the normal ranges for all instruments are in agreement. Sensor outputs have been set so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

Sensors

The general term "sensor" is used to refer to the three types of electrodes incorporated into the cartridges:

- Potentiometric
- Amperometric
- Conductometric

Sensors are thin film electrodes microfabricated onto silicon chips. Sensing functionality is imparted to each electrode by a number of chemically sensitive films coated over the active region of the electrodes.

Potentiometric Sensors

Potentiometry is the measurement of the difference in potential that exists between an indicator electrode and a reference electrode. Ion-selective electrodes (ISE) are examples of potentiometric sensors. The indicator electrode is designed to be sensitive to a particular ion in a solution. In cases where other ions are sensed by the system, selectivity coefficients can be used to correct for this interference. An enzyme can be added to an ISE to produce ions from analytes of interest that are not themselves ions.

The Nernst Equation

The Nernst equation relates the measured potential to the activity of the ion being measured.

$$E = E^\circ + RT/nF \ln a$$

Where E is the potential, E° is a constant dependent on the electrode/sensor system, R is the gas constant, T is the absolute temperature, F is Faraday's constant, (n) is the valance (positive or negative charge) for the ion being measured, and (a) is the activity of that ion.

The Nernst equation can be rewritten as:

$$E = E^\circ + S \log a$$

Where S replaces the constant term which defines the slope of the sensor. The slope is the change in millivolts per tenfold change in the activity of the analyte. For a positively-charged monovalent ion, the theoretical slope would be 59.1 mV at 25°C.

Activity Versus Concentration

Ion-selective electrodes measure activity rather than concentration. Activity (a) is related to concentration (c) through the activity coefficient (γ): $a = \gamma c$.

While ion activities, which reflect free rather than total ion concentrations, are the physiologically relevant quantity, activity values are converted to conventional concentration units so that values obtained by direct ISE measurements can be compared to values obtained from methods that measure total ion concentrations. The latter includes the indirect methods, which have activity coefficients close to unity or one, and flame photometric, atomic absorption and titration methods.

Amperometric Sensors

In amperometric measurements, a potential is applied to the measuring electrode while current generated by the resulting oxidation or reduction reactions in the test system is measured. The current generated is directly proportional to the concentration of the analyte. An enzyme can be added to a layer on or near an amperometric sensor to produce electroactive species from analytes of interest that cannot themselves be oxidized or reduced.

Conductometric Sensors

In a conductometric measurement, an alternating current is applied between two electrodes in contact with the test solution and the resulting voltage difference is measured. The conductivity of the solution is proportional to the magnitude of the voltage difference. In aqueous solutions, conductivity is dependent upon the concentration of electrolytes; an increase in the electrolyte concentration causes an increase in conductivity.

DETERMINATION OF TEST RESULTS

Determination of Analyte Concentration

Potentiometric and amperometric sensors are used for the determination of analyte concentration. For both sensors, the concentration of the analyte can be calculated using:

1) the known value of the analyte concentration in the calibrant solution,
2) the measured voltage (potentiometric) or current (amperometric) signal generated by the analyte in the calibrant, and
3) the measured signal generated by the analyte in the test solution.

For potentiometric sensors, the analyte activity in the sample is calculated from the Nernst equation according to:

$$E_{sample} - E_{calibrant} = S \log (a_{sample}/a_{calibrant}).$$

Complex solutions such as blood deviate slightly from Nernstian behavior due to interfering ions and matrix effects that result in junction potentials. By including selectivity coefficients in the Nernst equation (Nikolsky equation), these effects can be minimized. By characterizing the reference electrode in different solutions, effects of matrix on the reference junction potential can also be minimized.

It is known that direct methods read up to 7% higher than indirect methods in measuring the concentration of electrolytes. This is because there is an excluded volume occupied by plasma protein and lipids that is not considered in indirect measurements. Typically, however, the elevation of results is less than the full 7% because some of the analyte is bound to protein and other ions, and is not assayed by direct methods. For each analyte this discrepancy is characterized, and the result of the direct measurement is adjusted so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

DETERMINATION OF CELL CONCENTRATION

Hematocrit

In whole blood, plasma conducts electricity while the cellular constituents, red and white blood cells and platelets, do not. For a sample of a given electrolyte concentration, as the number of cells per unit volume of plasma increases, the conductivity of the sample decreases. The total cell concentration in whole blood can, therefore, be determined from:

1) the known electrolyte concentration of the calibrant,
2) the measured electrolyte concentration of the sample,
3) the measured conductivity of the calibrant and
4) the measured conductivity of the sample.

These measured quantities are determined using a combination of potentiometric and conductometric sensors.

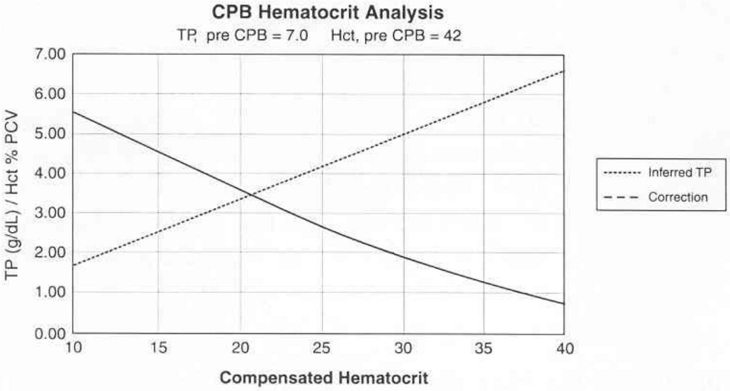
Direct measurement of hematocrit by the conductometric technique gives a result related to the non-conducting excluded volume fraction of the sample fluid. Red blood cell volume is the predominant component of the non-conducting volume, but proteins, lipids, and white blood cells also contribute. Elevated hematocrit readings are expected at abnormally elevated levels of these components. Decreased hematocrit readings are expected at abnormally low levels of protein, such as found in hemodiluted samples taken from patients on cardiopulmonary bypass.

Osmotic imbalance causes a discrepancy between direct (conductometric, spun) and indirect (Coulter) measurements because of variation in the mean cell volume.

CPB

Each time a cartridge containing a hematocrit sensor is used, the operator has the option of selecting, in addition to the sample type, the CPB compensation algorithm for samples with abnormally low protein levels. The CPB option is specifically intended for use when samples are collected from patients on cardiopulmonary bypass. However, the facility may validate its use for other patient populations known to have protein levels significantly lower than the normal adult population.

The CPB algorithm infers the total protein level by assuming the pump priming solution dilutes the hematocrit and total protein equally. Modeling the pre-pump hematocrit as 43 %PCV and the pre-pump total protein as 7.0 g/dL, the following graph indicates the inferred total protein and resultant correction.



For example:

- uncompensated Hct = 21 %PCV
- 21 %PCV = 0.50 of 42 %
- inferred total protein = 7.0g/dL x 0.50 = 3.5 g/dL
- 21 %PCV + 3 g/dL = 24 %PCV (CPB)

Limitations of the CPB Algorithm

The CPB algorithm is based upon a series of inferences:

- The algorithm models initial pre-pump values for total protein and hematocrit. Although actual initial values may be different than those used in the algorithm, typical deviations rarely affect the accuracy of the correction by more than 0.5 %PCV. More often than not, the actual values are consistent with a "pre-dilution" of the modeled values.
- The algorithm assumes that the pump priming solution has no added albumin or other colloid. The algorithm will tend to overcorrect if solutions with added colloids are utilized, though the size of the over-correction will seldom be more than 1 %PCV.
- Other therapies which affect the ratio of total colloids to hemaotcrit (administration of colloids, packed red blood cells, etc.) will affect the interference.

When to discontinue use of the CPB algorithm will depend on when the patient's total protein level reaches the pre-pump level.

It is recommended that each practice verify the hematocrit determination for cardiopulmonary bypass procedures so that the impact of these limitations upon a particular practice's protocol is understood.

DETERMINATION OF COAGULATION ENDPOINTS

ACT and PT/INR

In coagulation tests, the result that is reported is the time required for the process of coagulation to occur. To determine this time, there must be a detectable change in a sample parameter correlated to progression of the process. In traditional coagulation tests, endpoint detection typically relies on monitoring increases in either blood viscosity or plasma turbidity that occurs as thrombin converts fibrinogen to clotable fibrin. In an electrogenic test an electroactive marker that can be detected at either an amperometric or potentiometric sensor is used to indicate the endpoint. The marker is generated when a substrate that has been added to the test sample is acted upon by thrombin. As the coagulation reaction proceeds, the marker concentration increases, increasing the signal at the sensing electrode. The time required for generation of the marker correlates to the time required for conversion of fibrinogen. The coagulation endpoint can, therefore, be determined by monitoring the marker concentration. Unlike traditional coagulation tests, electrogenic tests will not be prolonged in samples with abnormally low (less than 100 mg/dL) fibrinogen levels.

QUALITY CONTROL AND THE I-STAT SYSTEM

Overview

Quality control, as a component of an overall quality assurance program, consists of tests and procedures for monitoring and evaluating the analytical performance of a measurement system to assure the reliability of patient test results.

As new technologies evolve, quality control regimens must match the requirements of the particular analytical system. i-STAT Corporation recognizes the importance of effective quality control for its analytical medical devices, and has developed a program that is tailored to the unique characteristics of the i-STAT System.

The i-STAT System performs blood analysis when a unit-use cartridge filled with a patient's sample is inserted into a handheld analyzer or Blood Analysis Module (as part of the Agilent Viridia Patient Monitoring System).

The measurement methodologies are electrochemical, using microfabricated sensors housed in each cartridge to measure analyte concentrations directly in a single whole blood sample (i.e., neither dilution nor reagent mixing steps are required).

Two characteristics of the i-STAT System, which distinguish it from traditional laboratory equipment, have significant impact upon the design of the quality control regimen: its intended user and the unit-use cartridge technology.

As the system is intended to be used by individuals not trained in laboratory science, the onus is upon the system's design to ensure that the quality of results is not dependent upon either user technique, skilled maintenance and calibration procedures, or the accompanying quality control regimens which ensure these procedures have been properly performed.

The use of unit-use cartridges frees the i-STAT System from these skilled maintenance and calibration procedures. It also allows for the design of a quality control system which automatically monitors those aspects of the measurement process which are the most likely to impact quality, including the characteristics of the individual sensors and the operator's actions.

i-STAT's quality control regimen has four aspects, resting on the foundation of a system design which reduces the opportunity for the type of error which traditional quality control regimens are designed to detect:

1) A series of automated, on-line quality measurements that monitor the sensors, fluidics and instrumentation each time a test is performed.
2) A series of automated, on-line procedural checks monitors the user each time a test is performed.
3) Liquid materials are used to verify the performance of a batch of cartridges when they are first received or when storage conditions are in question.
4) Traditional quality control measurements verify the instrumentation using an independent device, which simulates the characteristics of the electrochemical sensors in a way which stresses the performance characteristics of the instrumentation.

Similarities to Traditional Laboratory Quality Control Regimen

Although the more significant aspects of i-STAT's quality control regimen are the quality checks automatically performed with each unit-use cartridge, many principles of the quality control regimen are similar to traditional regimens.

Laboratory quality control methods are statistical. They assess the quality of the measurement process by intermittently inserting pseudosamples (controls) into the stream of samples being tested.

The approach implicitly assumes that the elements of the measuring system persist from run to run so that the repeatability and accuracy of the measurement of patient samples can be predicted by the repeatability and accuracy of pseudosamples.

The i-STAT regimen uses an analogous approach to monitor the part of the testing process which persists from run to run – the handheld analyzer or Blood Analysis Module.

An Electronic Simulator, which mimics the electrical characteristics of the signals produced by the sensors, is inserted into the handheld analyzer or Blood Analysis Module on a daily basis. The Simulator produces signals consistent with both very low and very high concentrations of each of the analytes. The analyzer or module causes the Simulator to change the signals via a control signal fed through the interconnect.

The software in the analyzer and module measures these signals as it would measure signals from a cartridge. The software checks the measurements against predetermined thresholds and indicates their acceptability to the user via a PASS/FAIL message.

All analyzers that pass the Electronic Simulator test are equivalent. Therefore, any representative number of analyzers that pass the simulator test may be used for compliance with regulatory and accreditation quality assurance procedures. These procedures include initial performance verification studies, calibration verification, proficiency testing, and method comparison studies.

An important aspect of the Simulator is that it mimics the sensitive nature of the sensor's signals to ensure that adjacent input channels within the analyzer or module maintain the required degree of electrical isolation from each other to prevent "crosstalk" (see US Patent #5124661 for details). This cannot be achieved by the traditional internal self-consistency checks characteristic of modern microprocessor-controlled instrumentation.

Comparison of this regimen to laboratory quality control procedures can seem confusing because it does not employ liquid control solutions. However, the principle is the same in that the traditional intermittent quality control measurements are applied to the persistent part of the system. In the case of the i-STAT System, only the instrumentation is persistent so only this portion is tested with an external challenge.

Further, use of an electronic quality control device has distinct quality advantages:

1) Non laboratory-trained individuals do not need to interpret control results because the analyzer and module software, expecting certain simulator signals, automates the interpretation. In comparison, many quality control regimens using liquid controls at the point of care are ineffective because an out-of-control result is easy to ignore.

2) Injecting signals into the analyzer or module allows very tight control limits to be set. Control limits using liquid controls at the point of care are generally very wide to allow for sensor-to-sensor variation.

The i-STAT Unit-Use Cartridge as an Element of Design Robustness for Point-of-Care Testing

The most important quality measure in the i-STAT System is that it is designed to reliably deliver quality results in the hands of individuals not trained in laboratory science. It addresses those aspects of the design in traditional laboratory-based equipment and other point-of-care devices which detract from robustness in the hands of these individuals.

1) In the interest of making batch processing efficient, laboratory devices make extensive use of components which are exposed to each test sample (sensors, tubing, etc.). These devices must be continuously recalibrated as successive samples interact with these elements. Quality control regimens are designed to detect incorrect or required calibrations.

   All elements which are exposed to the test sample are unit-use in the i-STAT System. Many of the out-of-control conditions which a laboratory quality control regimen is designed to catch simply do not exist.

   Furthermore, the use of unit-use devices is directly related to the design of i-STAT's quality approach. Each test begins with fresh sensors and a fresh calibrant fluid. The response of the sensors' signals to the fresh calibrant fluid is well characterized from a large database of tests run in i-STAT's manufacturing facility. If the sensor signal is uncharacteristic due to mismanufacture, mishandling or misstorage, the handheld analyzer or Blood Analysis Module's software will suppress the result (displays "***").

2) Many point-of-care devices require the non laboratory-trained user to interact directly with the sensing elements (paper strip technologies for example). Many Point-of-Care Coordinators rely heavily on the daily quality control regimen not only as a means for monitoring system performance, but more significantly, as a means for monitoring user proficiency.

The analyzer controls all fluid motions in the i-STAT System. The calibrant and sample are brought to the sensors under instrument control so that the user does not directly impact on the quality of the analytical process and therefore cannot impinge on the quality of the results.

Further, the analyzer uses a fluid sensor to electronically verify the proper flow of fluids within the cartridge on every run. This can easily be demonstrated by attempting to fool the system by:

- putting in too much sample
- putting in too little sample
- rerunning the same cartridge
- introducing an air segment into the fluid segment, etc. The analyzer will flag these conditions and not deliver a result.

3) The design of some unit-use point-of-care devices can allow an entire batch of unit-use devices to be affected by a single event, for example, by leaving a tube of paper strips open and exposed to a high humidity environment.

With the i-STAT System, each unitized device is sealed in a separate foil pouch and has its own individual history. The only external factor, which can create a shared history among cartridges, is temperature. This is controlled by appropriately monitoring the storage environment.

The Foundation of i-STAT's Quality Control Regimen – On-Line Tests

The fundamental backbone of i-STAT's quality regimen is the series of automatic checks performed each time a cartridge is run.

The tables below list the key elements and operations of the i-STAT System that are verified **each time** a cartridge is used.

For completeness, those operations which are qualified by the Electronic Simulator are also listed.

Unit-Use Cartridge

Verification	When Verified
Microfabricated Electrochemical Sensor Elements	
• verify sensors are present	Every cartridge use
• verify sensor characteristics are consistent with expectations of a properly manufactured and maintained device (by testing calibration fluid)	Every cartridge use
Calibration Fluid	
• verify fluid is present	Every cartridge use
• verify fluid is delivered free of bubbles	Every cartridge use
• verify fluid has proper concentration	Every cartridge use
Fluidic System	
• verify sample holding chamber is sealed	Every cartridge use
• verify fluid flowpaths are intact (no part of the analyzer or module comes into direct contact with fluid)	Every cartridge use
• verify waste chamber is not occluded	Every cartridge use
Elements that interact with the handheld analyzer or Blood Analysis Module	
• verify electrical contact pads (that allow access to sensor signals) are unoccluded	Every cartridge use
• verify internal element of cartridge that allows the analyzer or module to control the release of calibration fluid over the sensors is functioning properly	Every cartridge use
• verify internal element of cartridge that allows the analyzer or module to control the replacement of calibration fluid with sample is functioning properly	Every cartridge use

Handheld Analyzer and Blood Analysis Module

Verification	When Verified
Motorized Mechanical System	
• verify electrical contact is made with sensors on cartridge	Every cartridge use
• verify ability to properly move calibration fluid	Every cartridge use
• verify ability to properly move sample	Every cartridge use
Electrical Measurement System	
• verify voltage measuring system for potentiometric sensors	Electronic Simulator
• verify current measuring system for amperometric sensors	Electronic Simulator
• verify resistance measuring system for conductometric sensors	Electronic Simulator
Other	
• verify internal self-consistency of electronic systems	Every cartridge use
• verify fluid flow using the conductivity sensor	Every cartridge use
• verify function of transducers used for measuring barometric pressure	Every cartridge use
• verify function of the thermistors used to control chip temperature	Electronic Simulator

Operator Sample Handling/Cartridge

Verification	When Verified
Verify the cartridge inserted has not been previously used	Every cartridge use
Verify the calibrant pack has not prematurely ruptured	Every cartridge use
Verify the electronic contact pads are dry and uncontaminated	Every cartridge use
Verify the proper amount of sample was placed into the sample chamber	Every cartridge use
Verify the sample was properly positioned within the sample chamber	Every cartridge use
Verify the sample is free of included bubbles	Every cartridge use
Verify the sample is not clotted	Every cartridge use
Verify the sample chamber is properly sealed with the snap closure	Every cartridge use

Validating the Performance of the i-STAT System

Until recently, regulations and laboratory accreditation standards specified the use of traditional quality control regimens, including the daily use of liquid "control" materials.

As new technologies such as the i-STAT System have become available, the community has recognized the limitations of relying upon traditional regimens, prompting various regulatory and accreditation organizations to modify their standards accordingly.

Many of the newly drafted regulations and accreditation standards recognize the danger of denoting specific methods of achieving an effective quality control regimen. Additionally, specific methods cannot anticipate future technological changes, so many of the regulatory and accreditation organizations are changing their standards to place the responsibility of establishing and validating the quality system a laboratory employs on the laboratory director.

Quality control regimens should be established using information from the manufacturer and scientific literature.

It is important to validate the performance of the i-STAT System and the recommended quality control regimen to develop personal confidence in our approach to the challenges of putting a diagnostic device in the hands of individuals untrained in laboratory science.

Some of the regulatory and accreditation organizations recommend the daily use of liquid "control" materials for the first month of use, slowly stepping back the frequency as a database of performance information increases confidence levels. The number of lots of materials examined should also be considered when determining a validation protocol.

QUALITY CONTROL AND THE i-STAT COAGULATION TESTS

Operating Principles of the Coagulation Cartridge–Overview

The i-STAT coagulation cartridges measure the time required for complete activation of the coagulation cascade once initiated by the activator. Coagulation instruments determine this time by sensing a characteristic change in a measured property of the sample. In the i-STAT System the measured property is the concentration of an electroactive marker. The time to clot is indicated by a relative increase in the concentration as measured by an amperometric sensor.

i-STAT dries the activator and a precursor of the electrochemical marker (a substrate to the thrombin enzyme produced by the coagulation cascade) onto the wall of the reaction chamber during the manufacturing process. At the beginning of the test the system agitates the blood back and forth across the chamber wall to mix these reagents into the blood sample.

Quality System for Coagulation Cartridge

The critical performance feature of the coagulation cartridge centers on the repeatability of the reagent mixing process. The accuracy to which the reagent is mixed into the blood sample directly impacts the accuracy of the result.

The system quantitatively confirms the accuracy of the mixing step by monitoring the key parameters of mix uniformity, magnitude and timing. These quality tests are performed on each coagulation cartridge.

i-STAT's microfabrication production processes are inherently capable of creating sensors with highly reproducible characteristics. For the measurement of blood gases, electrolytes and chemistries, this means that the i-STAT System requires only a one-point calibration, using a calibrant solution packaged in the cartridge, to meet the demanding requirements for clinical accuracy. As described in the Quality Control section of the i-STAT System Manual, the calibrant solution is also used to verify the integrity of the sensors as a key component of the quality system.

For the measurement of ACT and PT, the required accuracy for the amperometric sensor to detect the relative increase in concentration of the electroactive marker is more modest. A calibrant solution is required neither for a one-point calibration nor to verify the wetup characteristics of the sensor. Instead, the magnitude and rate of change of current is assessed quantitatively throughout the test in order to verify the quality of the mix, and the integirity of both the sensor and the reagent coating.

Regulatory Aspects of the Quality System for Coagulation

Alternatives to traditional quality systems have been developed that are suitable for ensuring the performance of unit-use in-vitro diagnostic systems. These alternative systems rely upon a variety of internal self-tests and electronic/optical checks. As unit-use devices have become more widespread in clinical practice, regulations and guidance documents have adapted to recognize the effectiveness of these alternative quality systems, albeit with some variation. For example, some state regulations require that the alternative quality system include an on-board "wet" control. The i-STAT Quality System for the coagulation test is able to address this requirement even though the cartridge does not contain an on-board wet calibration fluid. The quantitative confirmation that the activator and the marker are accurately mixed into the blood sample is a "wet" test that acts as a control of the most critical aspect of the coagulation test.

Electronic Quality Control

i-STAT's electronic simulator (both the internal and external versions) check the amperometric and conductivity circuitry used in the coagulation tests at multiple levels. The instrument checks the accuracy of the measurement of elapsed time each time a test is run by comparing the clock rates from two independent clocking circuits. The instrument also runs a battery of general instrument checks during each test.

DOWNLOADER PROGRAMMING AND WIRING 21

PROGRAMMING THE NETWORK DOWNLOADERS

This section includes procedures to configure the network Downloaders to transmit data between the i-STAT 1 Analyzers and the Central Data Station (CDS) program as well as from other peripheral devices to the CDS or other PC.

Preparation

1. Determine for each Downloader: IP Address, Gateway Address, and Subnet Mask.
2. Determine for the Workstation: The IP Address of the Point-of-Care Central Workstation and the Central Data Station service port for i-STAT 1 Analyzer transmissions (typically 6004).

Configure a Terminal Session

1. Run a terminal emulation program, such as HyperTerminal, and choose the following port settings:

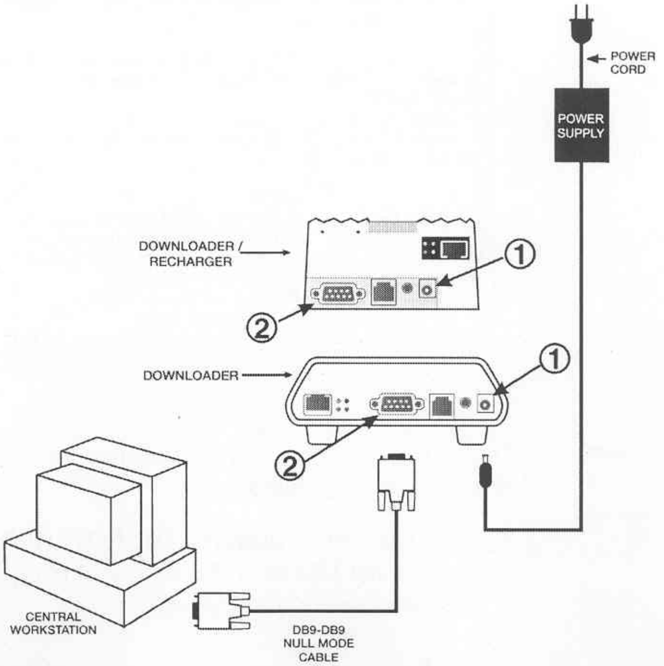
Bits per second: **9600**
Data bits: **8**
Parity: **None**
Stop Bits: **1**
Flow Control: **None**

Connect to and Program the Downloader

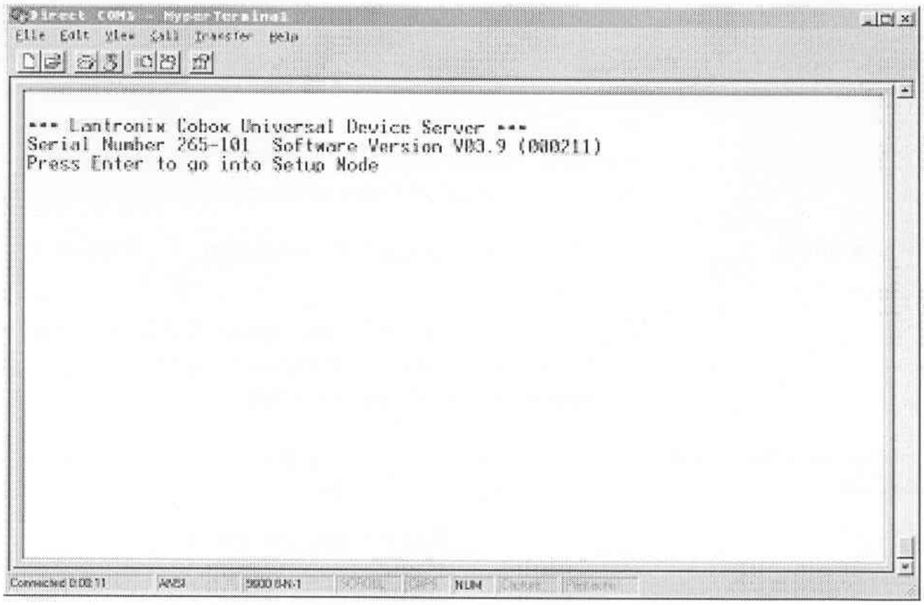
1. Connect one end of a Null-Modem Cable to the DB9 Port on the Downloader and connect the other end to the COM port selected in the session above to the Point-of-Care Central Workstation as shown below. **Do not apply power to the Downloader at this time.**

① Power In

② DB9

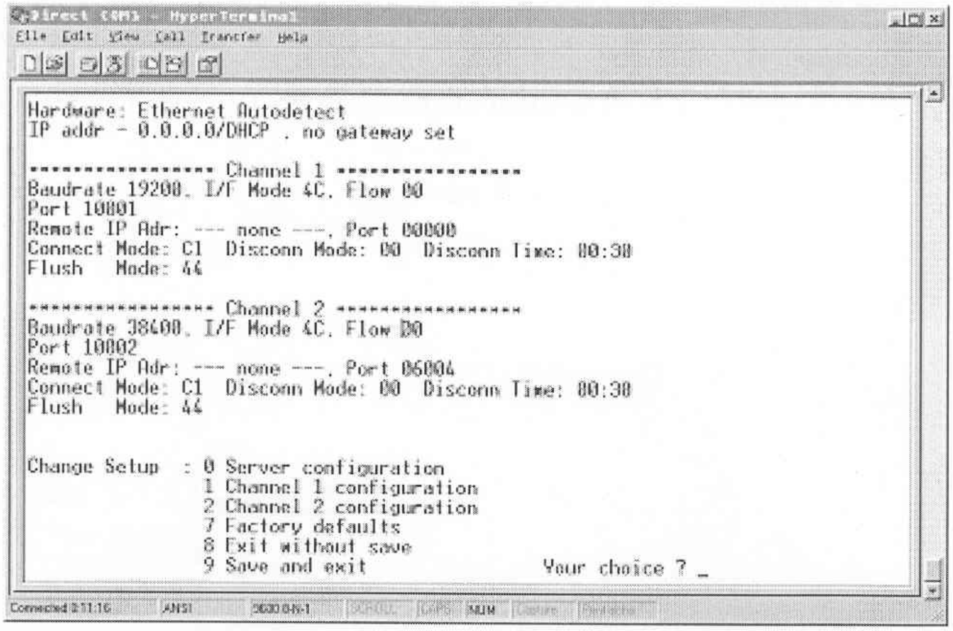


2. While holding down the **x** key on the PC keyboard, apply power to the Downloader. When the following screen is displayed release the **x** key:


Direct COM1 - HyperTerminal
File Edit View Call Transfer Help
Connected 0:00:11
ANSI
9600 8-N-1
SCROLL
CAPS
NUM
Capture
Print echo

```
*** Lantronix Cobox Universal Device Server ***
Serial Number 265-101  Software Version V03.9 (000211)
Press Enter to go into Setup Mode
```

3. Press the Enter key immediately to enter the Setup Mode:


Direct COM1 - HyperTerminal
File Edit View Call Transfer Help
Connected 0:11:16
ANSI
9600 8-N-1
SCROLL
CAPS
NUM
Capture
Print echo

```
Hardware: Ethernet Autodetect
IP addr - 0.0.0.0/DHCP , no gateway set

****************** Channel 1 *****************
Baudrate 19200, I/F Mode 4C, Flow 00
Port 10001
Remote IP Adr: --- none ---, Port 00000
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

****************** Channel 2 *****************
Baudrate 38400, I/F Mode 4C, Flow 00
Port 10002
Remote IP Adr: --- none ---, Port 06004
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

Change Setup  : 0 Server configuration
                1 Channel 1 configuration
                2 Channel 2 configuration
                7 Factory defaults
                8 Exit without save
                9 Save and exit               Your choice ? _
```

Configure Server Parameters

Each network Downloader requires a static IP Address, a Gateway Address, and, if required, a Subnet Mask.

Note: **Failure to assign a static IP address to the downloader could result in an i-STAT 1 Analyzer being programmed with an inappropriate customization profile.**

The following describes how to configure the network Downloader's server parameters.

1. Determine the following site specific information for this Downloader:
    - IP Address (Example: 10.10.12.142 used below)
    - Gateway Address (Example: 10.10.12.1 used below)
    - Netmask (Example: 8 for 255.255.255.0 used below)
2. At the **Your choice?** prompt, Select **0** for Server Configuration and enter the information chosen for this Downloader.
3. At each of the prompts enter the bold-faced value.

    Note: If the information to be entered is the same as the default value, press the Enter key.

    - IP Address: (000)**10**.(000) **10**.(000)**12**.(000)**142**
    - Set Gateway IP Address: (N) **Y**
    - Gateway IP addr: (000)**10**.(000)**10**.(000)**12**.(000) **1**
    - Netmask: Number of Bits for Host Part (00) **8**

      Note: The Netmask is configured as the number of host bits required based on the subnet being used.

    - Change telnet config password: (N) **N**

Default Netmasks for Standard IP Networks

SUBNET MASK	HOST BITS	NETWORK TYPE
255.0.0.0	24	Class A
255.255.0.0	16	Class B
255.255.255.0	8	Class C

Netmasks for Other Networks

SUBNET MASK	HOST BITS	SUBNET MASK	HOST BITS
255.255.255.252	2	255.255.192.0	14
255.255.255.248	3	255.255.128.0	15
255.255.255.240	4	255.255.0.0	16
255.255.255.224	5	255.254.0.0	17
255.255.255.192	6	255.252.0.0	18
255.255.255.128	7	255.248.0.0	19
255.255.255.0	8	255.240.0.0	20
255.255.254.0	9	255.224.0.0	21
255.255.252.0	10	255.192.0.0	22
255.255.248.0	11	255.128.0.0	23
255.255.240.0	12	255.0.0.0	24
255.255.224.0	13		

Configure Channel 2

Channel 2 provides network access for the i-STAT 1 Analyzer data transmissions to the i-STAT Central Data Station running on the Data Manager. This section describes how to set up parameters for Channel 2.

1. Determine the following information:
    - The IP address of the Data Manager. (Example: 10.10.12.184)
    - The service port number set to receive transmissions from the i-STAT 1 Analyzer (typically 6004).
2. At the **Your choice ?** prompt, Select **2** (Channel 2 Configuration).
3. At each of the prompts enter the following bold-faced value:

    Note: If the information to be entered is the same as the default value, press the Enter key.

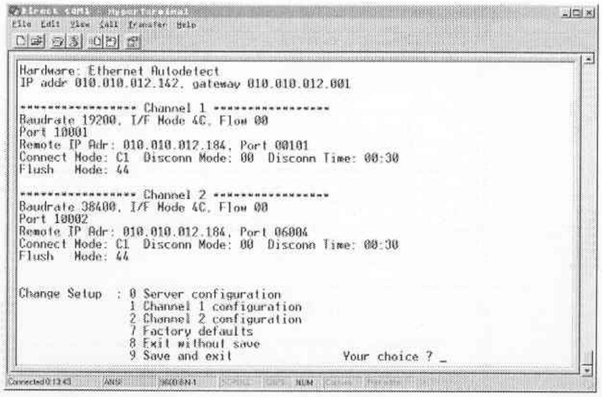
    - Baudrate (38400) ? **38400** (***must be set to 38400***)
    - I/F Mode (4C) ? (***press <Enter> key***)
    - Flow (00) ? (***press <Enter> key***)
    - Port No (10002) ? (***press <Enter> key***)
    - ConnectMode (C1) ? **C1** (***must be set to C1***)
    - Auto increment source port (N) ? **N** (***press <Enter> key***)
    - Remote IP Address : (000)**10**.(000)**10**.(000)**12**.(000) **184**

      Note: Set Remote IP Address to the IP Address of the Point-of-Care Central Workstation.
    - Remote Port (06004) ? **6004**

      Note: Remote Port refers to i-STAT 1 service port defined in the Central Data Station program.
    - DisConnMode (00) ? (***press <Enter> key***)
    - FlushMode (44) ? **44** (***must be set to "44"***)
    - DisConnTime (00:30) ? **00:30** (***Disconnect time must be 30 seconds)***
    - SendChar 1 (00) ? (***press <Enter> key***)
    - SendChar 2 (00) ? (***press <Enter> key***)

Verify and Save Settings

1. When the Summary screen appears, verify that the information you entered is correct. If it is not, fix the appropriate settings and continue.



```
Hardware: Ethernet Autodetect
IP addr 010.010.012.142, gateway 010.010.012.001

***************** Channel 1 *****************
Baudrate 19200, I/F Mode 4C, Flow 00
Port 10001
Remote IP Adr: 010.010.012.184, Port 00101
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

***************** Channel 2 *****************
Baudrate 38400, I/F Mode 4C, Flow 00
Port 10002
Remote IP Adr: 010.010.012.184, Port 06004
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44


Change Setup  : 0 Server configuration
                1 Channel 1 configuration
                2 Channel 2 configuration
                7 Factory defaults
                8 Exit without save
                9 Save and exit             Your choice ? _
```

2. Save the settings by selecting **9** (Save and Exit) at the **Your choice ?** prompt.
3. Remove power and connect the Downloader in its intended location.

Troubleshooting

If a wrong number is entered, which cannot be corrected, press the **Enter** key until the session is completed and start from the beginning again.

WIRING THE DOWNLOADERS

Overview

This section includes diagrams to make a connection between the Downloaders and the Data Manager and to connect a printer to the Downloaders.

Caution

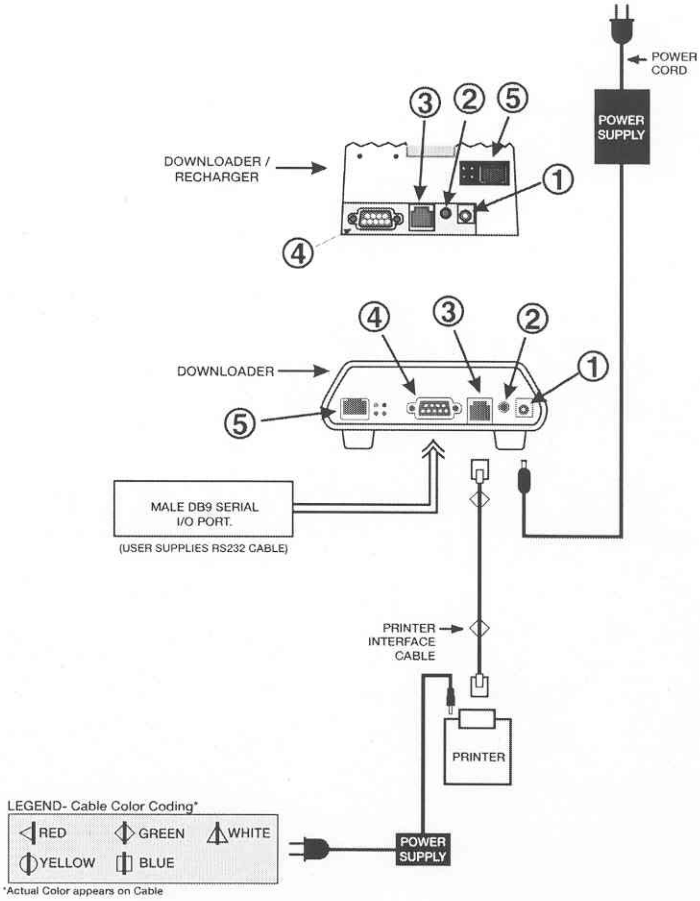
Non i-STAT devices may not be connected to the Downloader and Downloader/ Recharger. Only the Martel printer may be connected to the Downloader using cables supplied by i-STAT.

Connecting the Network Downloader

Option 1: The following diagram shows how to connect the portable printer to the network Downloader for communication. Parts required are:

- Printer Interface Cable
- Printer Power Adapter

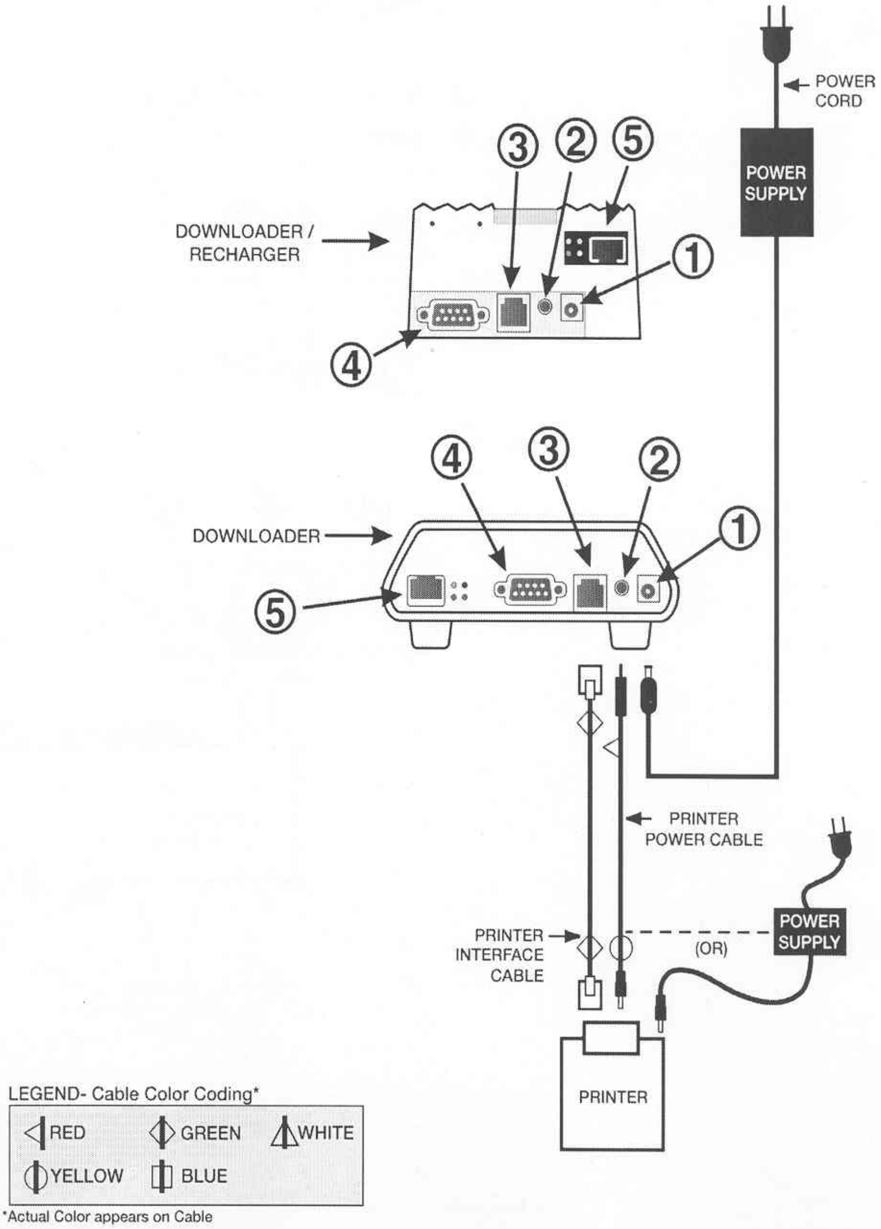
① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9
⑤ RJ45 (network)


POWER CORD
POWER SUPPLY
③ ② ⑤
DOWNLOADER / RECHARGER
①
④
④ ③ ②
DOWNLOADER
①
⑤
MALE DB9 SERIAL I/O PORT.
(USER SUPPLIES RS232 CABLE)
PRINTER INTERFACE CABLE
PRINTER
POWER SUPPLY
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

Option 2: The following diagram shows how to connect the portable printer to the network Downloader for power and communication. Parts required are:

- Printer Interface Cable
- Printer AC Adapter or Printer Power Cable

① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9
⑤ RJ45 (network)


POWER CORD
POWER SUPPLY
③ ② ⑤
DOWNLOADER / RECHARGER
①
④
④ ③ ②
DOWNLOADER
①
⑤
PRINTER POWER CABLE
PRINTER INTERFACE CABLE
(OR)
POWER SUPPLY
PRINTER
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

Connecting the Serial Port Downloader

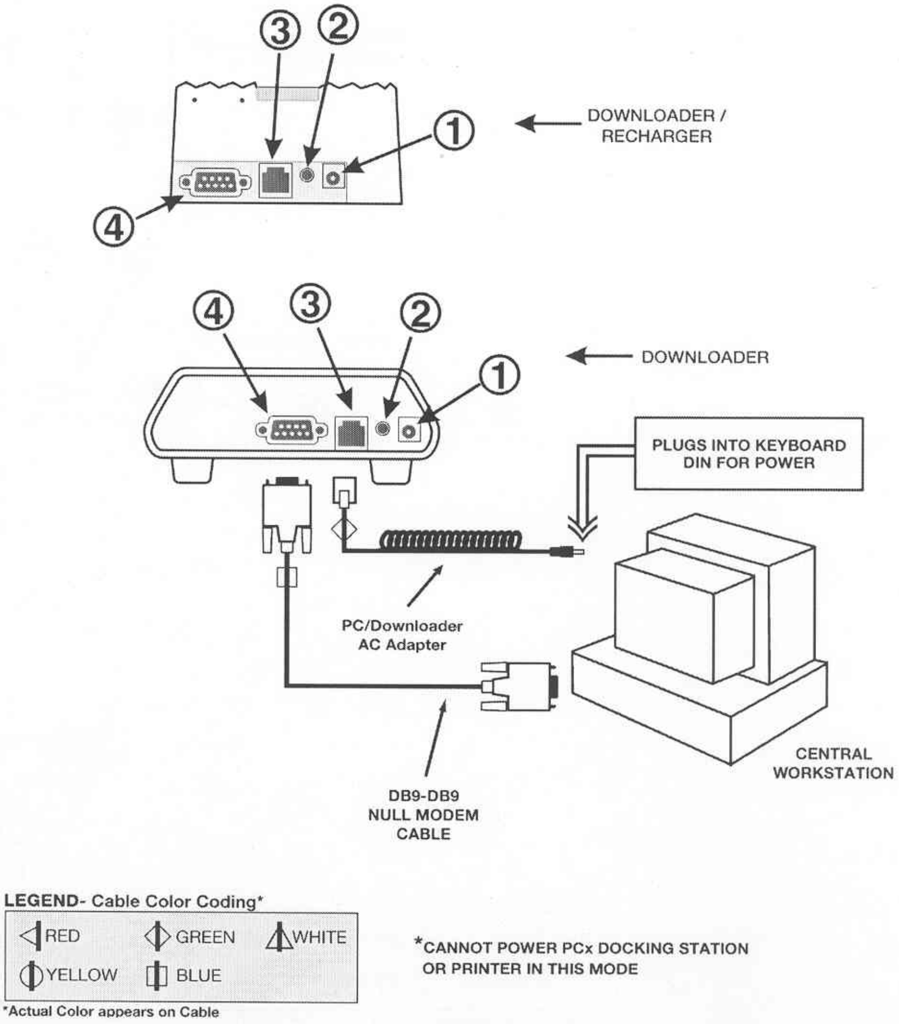
Option 1: The following option is for downloading/uploading only and can be used when there is no power outlet available for the Downloader or Downloader/Recharger.

In this particular configuration, both recharging LED lights will be lit. The primary recharging LED will blink red and the alternate will be steady green. This is typical behavior, and does not indicate that any charging is taking place. In fact, batteries cannot be charged in the Downloader/Recharger in this configuration.

The following diagram shows how to connect a serial downloader locally to the Data Manager. Parts required are:

- PC/Downloader Adapter
- DB9-DB9 Null Modem Cable

① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9

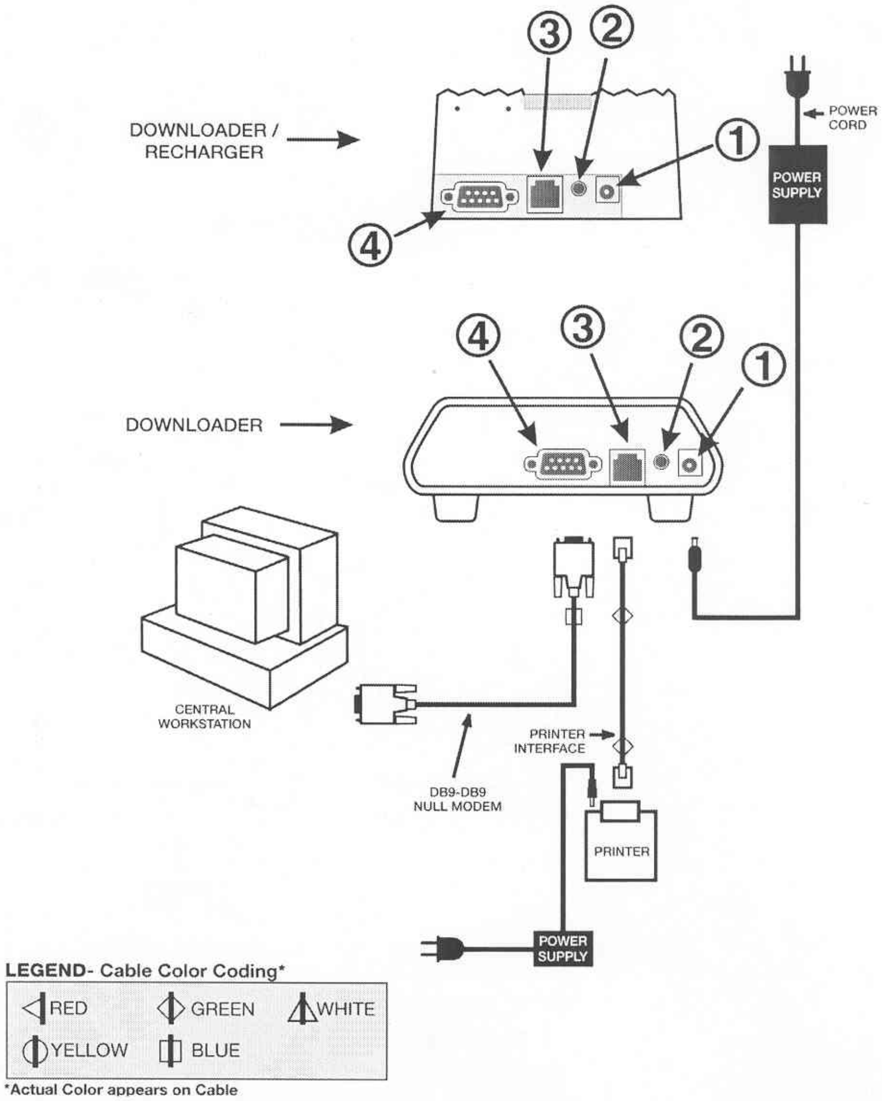

③ ②
①
DOWNLOADER / RECHARGER
④
④ ③ ②
①
DOWNLOADER
PLUGS INTO KEYBOARD DIN FOR POWER
PC/Downloader AC Adapter
CENTRAL WORKSTATION
DB9-DB9 NULL MODEM CABLE
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

*CANNOT POWER PCx DOCKING STATION OR PRINTER IN THIS MODE

Option 2: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for communication. Parts required are:

- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer AC Adapter

① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9


DOWNLOADER / RECHARGER
③
②
①
④
POWER CORD
POWER SUPPLY
DOWNLOADER
④
③
②
①
CENTRAL WORKSTATION
DB9-DB9 NULL MODEM
PRINTER INTERFACE
PRINTER
POWER SUPPLY
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

Option 3: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for power and communication. The printer can also be powered by its own AC adpater. Parts required are:

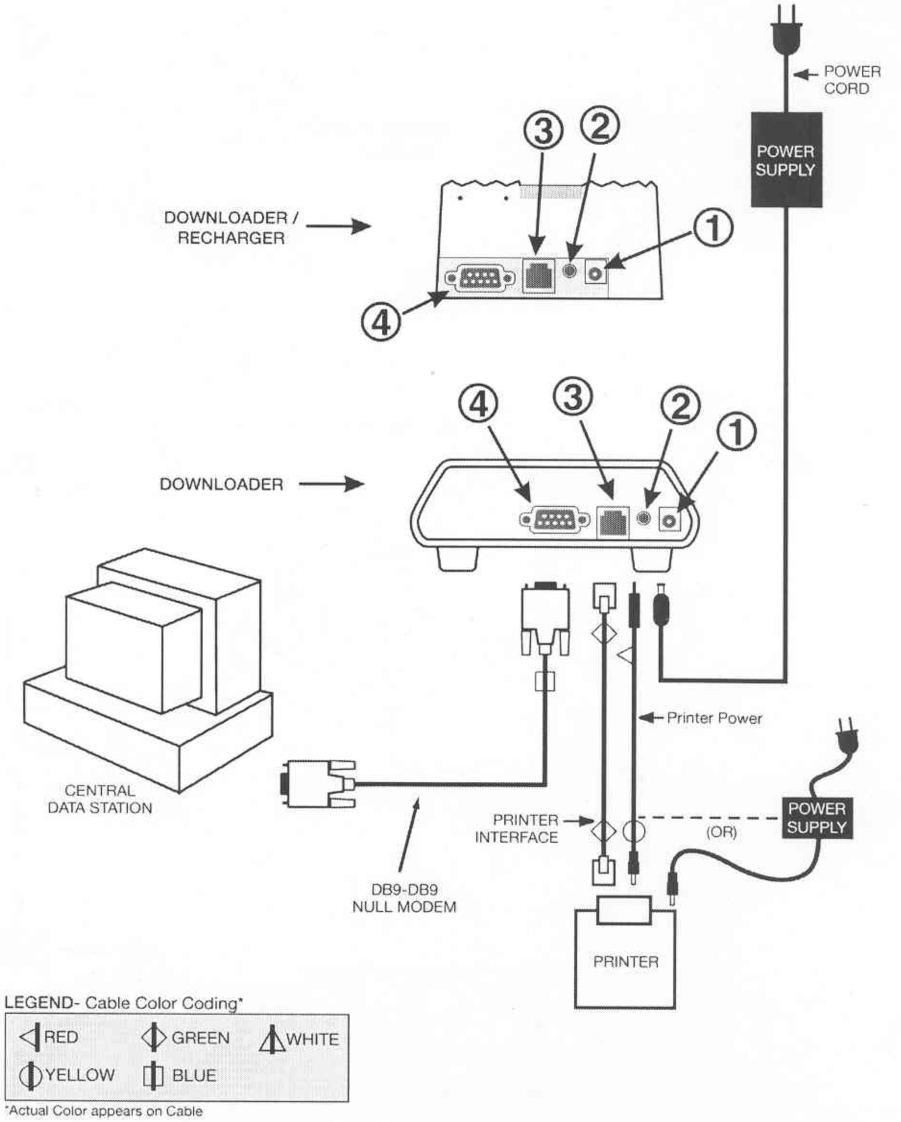
- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer Power Cable or Printer AC Adapter

① Power In

② Power Out

③ RJ12 (printer interface)

④ DB9


POWER CORD
POWER SUPPLY
③
②
DOWNLOADER / RECHARGER
①
④
DOWNLOADER
④
③
②
①
Printer Power
CENTRAL DATA STATION
PRINTER INTERFACE
(OR)
POWER SUPPLY
DB9-DB9 NULL MODEM
PRINTER
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

CENTRAL DATA STATION 5

22

ABBOTT POINT OF CARE INC. LICENSE AGREEMENT AND WARRANTY FOR CENTRAL DATA STATION PROGRAM

EULA

For new users of CDS software the license and warranty information in the End User License Agreement (EULA) will be in effect.

License

The i-STAT Central Data Station software is licensed to the authorized user by Abbott Point of Care Inc.. Portions of the software are licensed to you by Abbott Point of Care Inc. under sublicense from other original software providers. By accepting and using this software, the user/licensee agrees to the following:

- The user/licensee will not make copies of the software programs or any of the program software files generated by the programs, the manual or other documentation except for archive copies made as part of user/licensee's regular back-up procedures.
- The user/licensee will protect the programs from unauthorized use, illegal reproduction (including reproducing any of the software files generated by the programs) or illicit distribution.
- The user/licensee will not change or reverse engineer the programs or any of their software files by debugging, decompiling, disassembling, reprogramming, rewriting the programs' macros, revising the programs' forms or any other means.

If the user/licensee makes any use, transfer or disclosure of the programs in violation of any of the foregoing, the sub-license will, at the option of Abbott Point of Care Inc., immediately terminate without demand or notice and the user/licensee will immediately give to Abbott Point of Care Inc. the programs, the manuals and all copies thereof in the user/licensee's possession.

Warranty

Abbott Point of Care Inc. warrants the licensed software and accompanying physical documentation to be free of defects for a period of thirty days from the date of installation. If notified of defects within the warranty period, Abbott Point of Care Inc. will replace the defective software or documentation as soon as practical for the nature of the defect. The remedy for breach of this warranty is limited to replacement and shall not encompass any other damages including but not limited to loss of profit, and special, incidental, consequential or other similar claims. Abbott Point of Care Inc. specifically disclaims all other warranties, expressed or implied, including but not limited to implied warranties of merchantability and fitness for a particular purpose, with respect to the software, accompanying documentation and the license granted herein.

INSTALLATION OF THE CENTRAL DATA STATION

Hardware

The PC on which the CDS software resides must meet specifications provided by Abbott Point of Care Inc. and should be installed following the PC manufacturer's directions. Install the printer if applicable.

Software Installation: License Key

A license key is required to install the Central Data Station software. The license key ensures that the end user agrees to the License Agreement which is displayed during installation. To obtain the license key, follow the instructions on the screen and listed below.

1. Insert the CDS CD and the installation will begin automatically.
2. Click **Next>** in the Welcome dialog.
3. The End-User License Agreement will be displayed. Read the agreement and if you agree to abide by the agreement, click **Yes** to proceed with the installation. If you do not agree, click **No** to abandon the installation.
4. Record the serial number of the CDS displayed in the *Enter License Key* dialog.
5. Go to the Abbott Point of Care Inc. web site at http://www.abbottpointofcare.com and click on the i-STAT panel in the lower left corner of the screen. Click on the link under **CDS Key Generator** in the right hand column. You can also access this link directly at http://www.abbottpointofcare.com/cdslicense. (In the USA, the license key can also be obtained from Technical Support.)
6. If you are already registered, skip to step 8. If you are not registered, fill out the required information, select Basic Access, and click **Register.**
7. Go back to the i-STAT web site as directed in step 5.
8. Enter your username and password and click **Login**.
9. You may now enter the serial number recorded in step 4, and click **Submit**.
10. If successful, a message will appear indicating that your key has been e-mailed to the address with which you registered.
11. Obtain the key from the e-mail and enter it in the space provided on the CDS.
12. Click **Next** to proceed with the installation.

Caution

The use of other software that was not provided as part of the system on the same PC with the Central Data Station software may compromise the system, including permanent loss of patient records.

Site Specific Customization of the CDS

During installation, the CDS must be customized to properly communicate with i-STAT 1 Downloaders and Downloader/Rechargers, i-STAT IR Links and Philips Medical Systems Blood Analysis Modules throughout the hospital. The procedure to customize the CDS is described under the Customization section below.

The date displayed with results can be changed to any Short Date format and separator listed in the computer's Control Panel under Regional Options (or something similar, depending on the version of Microsoft Windows in use). If an unsupported format or separator is detected, the user will be notified and given the opportunity to change to a supported format/separator combination.

Connectivity

Basic information needed to connect the Downloaders, Downloader/Rechargers, and the portable printer to the PC are in the Downloader Wiring and Programming section of this manual.

For assistance in programming the Downloader, Downloader/Recharger and IR Links, contact your i-STAT support representative.

Interface

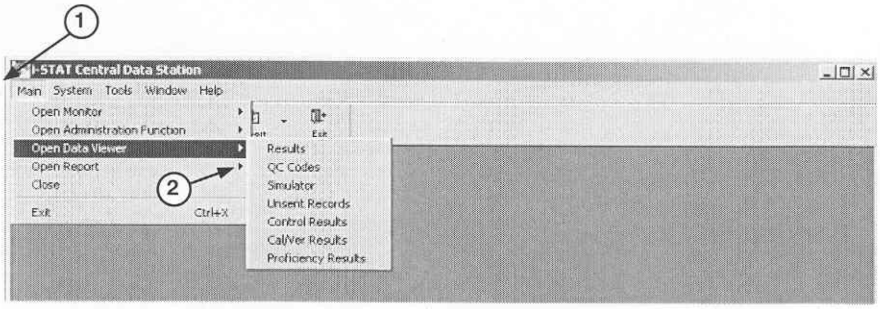
Basic information on interfacing can be found in the "Interface" paragraph under "Customization of the Central Data Station" in this section of this manual and in section 8.

Overview

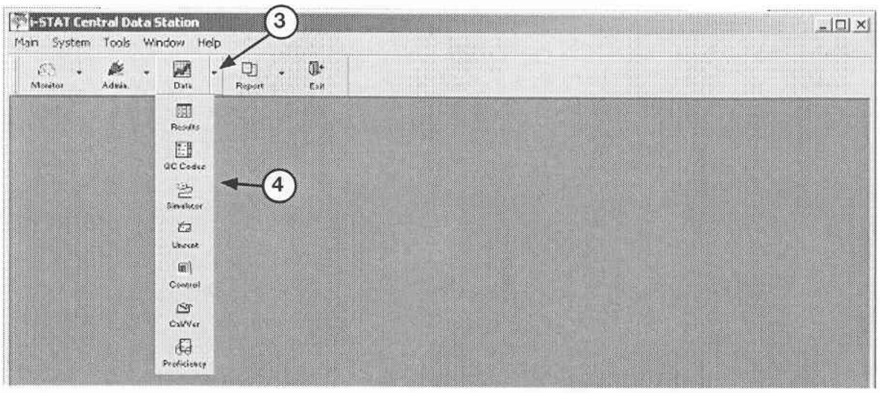
The CDS software follows typical Microsoft® Windows® conventions and procedures. The illustrations below are used to point out the use of the menu bar, toolbars, tabs and buttons.

Selecting Menu Options

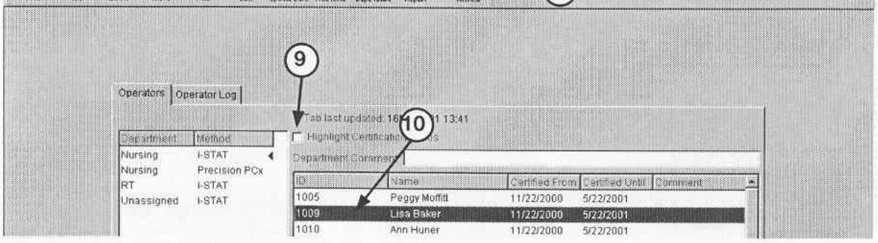
Clicking an item on the menu bar (1) will drop down the menu for that item. If any of the items in the drop down menu has a submenu, the submenu will open to the right of the ▶symbol next to the item when the item is highlighted (2).


①
i-STAT Central Data Station
Main
System
Tools
Window
Help
Open Monitor
Open Administration Function
Open Data Viewer
Open Report
Close
Exit
Ctrl+X
②
Results
QC Codes
Simulator
Unsent Records
Control Results
Cal/Ver Results
Proficiency Results
Exit

Clicking the ▼ beside a toolbar button (3) will drop down a submenu toolbar (4).


i-STAT Central Data Station
③
Main
System
Tools
Window
Help
Monitor
Admin.
Data
Report
Exit
Results
QC Codes
④
Simulator
Unsent
Control
Cal/Ver
Proficiency

Clicking the desired menu option will open the item's window or will perform the item's function. The menu items and toolbar for the active window will be displayed (5).


i-STAT Central Data Station - [Operator Workspace]
Main
System
Operator
Tools
Window
Help
Monitor
Admin.
Data
Report
Exit
Print
Add
Delete
Move
Find
Edit
Update Cert.
Add Note
Dept. Name
Report
Refresh
⑤
⑨
Operators
Operator Log
Tab last updated: 16
⑩
1 13:41
☐ Highlight Certification
s
Department Comment

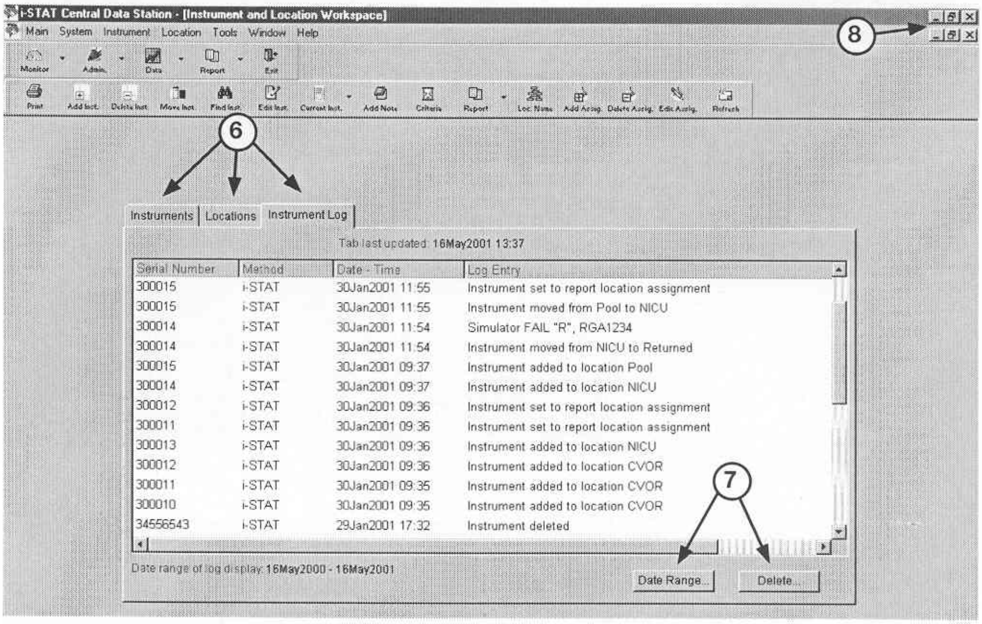
Department	Method
Nursing	i-STAT
Nursing	Precision PCx
RT	i-STAT
Unassigned	i-STAT

ID	Name	Certified From	Certified Until	Comment
1005	Peggy Moffitt	11/22/2000	5/22/2001	
1009	Lisa Baker	11/22/2000	5/22/2001	
1010	Ann Huner	11/22/2000	5/22/2001	

Selecting Functions in a Window

Tabs: A window may have several functional groupings that are contained in tabs (6) with multiple pages. Clicking the text on the tab will display the corresponding page.

Buttons: Use to activate a function within a window (7) or to confirm (OK) or cancel a function or to manipulate a window. All windows can have the following buttons in the upper right hand corner (8):


i-STAT Central Data Station - [Instrument and Location Workspace]
Main System Instrument Location Tools Window Help
Monitor
Admin.
Data
Report
Exit
Print
Add Inst.
Delete Inst.
Move Inst.
Find Inst.
Edit Inst.
Current Inst.
Add Note
Criteria
Report
Loc. Name
Add Assig.
Delete Assig.
Edit Assig.
Refresh
8
6
Instruments
Locations
Instrument Log
7
Date Range...
Delete...

Tab last updated: 16May2001 13:37

Serial Number	Method	Date - Time	Log Entry
300015	i-STAT	30Jan2001 11:55	Instrument set to report location assignment
300015	i-STAT	30Jan2001 11:55	Instrument moved from Pool to NICU
300014	i-STAT	30Jan2001 11:54	Simulator FAIL "R", RGA1234
300014	i-STAT	30Jan2001 11:54	Instrument moved from NICU to Returned
300015	i-STAT	30Jan2001 09:37	Instrument added to location Pool
300014	i-STAT	30Jan2001 09:37	Instrument added to location NICU
300012	i-STAT	30Jan2001 09:36	Instrument set to report location assignment
300011	i-STAT	30Jan2001 09:36	Instrument set to report location assignment
300013	i-STAT	30Jan2001 09:36	Instrument added to location NICU
300012	i-STAT	30Jan2001 09:36	Instrument added to location CVOR
300011	i-STAT	30Jan2001 09:35	Instrument added to location CVOR
300010	i-STAT	30Jan2001 09:35	Instrument added to location CVOR
34556543	i-STAT	29Jan2001 17:32	Instrument deleted

Date range of log display: 16May2000 - 16May2001

□ This button causes the window to be maximized.

_ This button causes the window to be minimized.

🗗 This button causes the window to be moveable and resizable.

✕ This button causes the window to close.

If a window does not have a close button, it can be closed by selecting **Main** then **Close** on the menu bar.

Check boxes: Click the box to enable or disable a single option (9).

Radio buttons: Click the circle to select from a list of mutually exclusive options.

Highlight bar: Use to select the line or lines on which to apply a function (10).

Drop down list: Click the ▼ button to drop down a list or scroll downward in a window.

Refreshing/ Updating the Data in a Window

The **Refresh** toolbar button refreshes the data content in the active window with the most recent data available. The refresh function is also available under the Window option on the menu bar. Pressing **F5** will also refresh the data.

Sorting Data in a Window

In most cases, when data is presented in a table, clicking a column header will sort the display based on the data in that column. In the Data Viewers, repeating values, such as a patient ID, will be sorted in descending Date/Time order. Clicking the header again will reverse the order of the sort. To return the data to chronological order, click the Date-Time column header.

Selecting Multiple Lines

In many functions, multiple lines can be selected for the desired action. To select consecutive multiple lines, click the first line and, while holding down the **Shift** key, click the last line. To select multiple lines that are not consecutive, click the desired lines while holding down the **Ctrl** key.

Opening Multiple Windows

Multiple windows can be open at the same time. The **Windows** item on the menu bar can be used to select the desired window from the list of open windows and bring it to the forefront. Close windows by clicking the **Close** button at the top right of the window or by selecting **Close** from the **Main** menu.

Column Ordering

Columns in the Data Viewers can be placed in any order. Use the mouse to grab a column header and drag the column to the desired position.

Column Widths

To adjust a column's width in Data Viewers, place the mouse pointer on the edge of the column header. When the mouse pointer turns into two arrows, hold the left mouse key and drag column to the desired width.

Toolbars

Helpful Hint!

Select **Tools ➪ Customize Toolbars...** to select options for the way toolbars appear. Checking **Large Buttons** displays descriptive text under toolbar buttons. This may be helpful while learning the application. Checking **Show Tooltips** displays a description of a button when the mouse pointer is placed over a toolbar button.

CUSTOMIZATION OF THE CENTRAL DATA STATION

Overview

The Customization options are:

Site Information	Institution name and technical support phone number
Serial Ports	Enables/Disables serial communications and allows individual ports to be selected and configured
Network	Enables/Disables network communications and allows specification of TCP port numbers
Interface	Enables/Disables external interfacing and allows protocol to be selected
Options	Allows various general system behaviors to be specified
Security	Enables/Disables the CDS Security features which allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application.

To access the Customization screen, close the CDS application, access the Run dialog box by clicking **Start** ➪ **Run....** Type **wcds32 config** at the **Open:** prompt, then click **OK**.

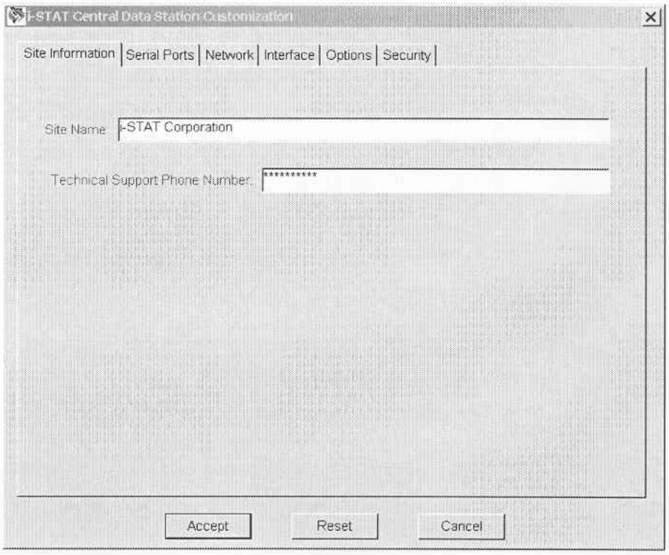
If **Run...** is not on the **Start** menu, double click the **Command Prompt** shortcut. At the **C:\>** prompt in the window that opens, type **c:\istat32\bin\wcds32.exe config** and press **Enter**.

When the Customization screen appears, click a tab to display the desired tab page. The information in each field can be specified. When all tabs are customized as desired, click the **Accept** button to save the information. Click the **Reset** button to disregard changes and restore the previous information. Click the **Cancel** button to ignore any changes and retain the current settings. When customization is complete, the CDS application will open automatically.

Site Information

A site name and address of up to 60 characters can be entered into this field.

The appropriate Technical Support Phone Number for the country will be listed or can be entered.



Site Name: i-STAT Corporation

Technical Support Phone Number: **********

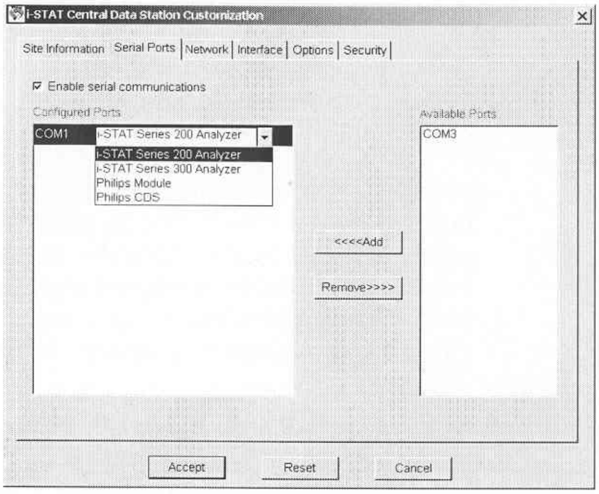
Serial Ports

The Central Data Station program resides on a PC with multiple serial ports (DB9). Available ports will automatically be listed under **Available Ports** on the Serial Ports tab page. The following components can be connected to the Central Data Station via serial ports:

- ☐ **i-STAT Series 200 Analyzer:** IR Link transmits data to and from the i-STAT Portable Clinical Analyzer.
- ☐ **i-STAT Series 300 Analyzer:** Downloader or Downloader/Recharger transmits data to and from the i-STAT 1 Analyzer.
- ☐ **Philips Module:** a local connection to the CDS is needed to transmit software updates and customization profiles to the Blood Analysis Module.
- ☐ **Philips CDS:** The CDS server transmits patient data from the Blood Analysis Module to the Data Manager.

Click the **Enable serial communications** box to check it and enable serial communications.

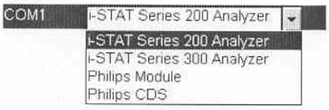
Click the desired port(s) under **Available Ports** and click the **<<<<Add** button. The port(s) will now be listed under **Configured Ports.**


i-STAT Central Data Station Customization
Site Information
Serial Ports
Network
Interface
Options
Security
Configured Ports
Available Ports
COM3
i-STAT Series 200 Analyzer
i-STAT Series 300 Analyzer
Philips Module
Philips CDS
<<<<Add
Remove>>>>
Accept
Reset
Cancel

☑ Enable serial communications

COM1 i-STAT Series 200 Analyzer

Click the port and select an instrument for that port.


i-STAT Series 200 Analyzer
i-STAT Series 300 Analyzer
Philips Module
Philips CDS

COM1 i-STAT Series 200 Analyzer

Serial ports on the PC might also be needed for a local PCx Docking Station and connection to an interface.

Network

Click the **Enable network communications** box to check it and enable network communications.

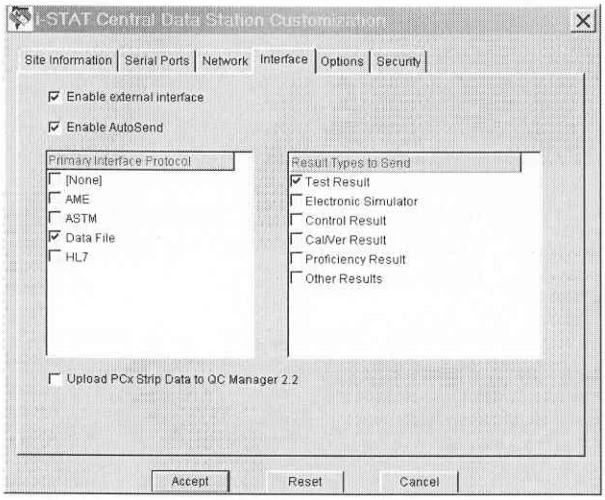
The default TCP service port assignments are listed in the Network tab page. If not using the default ports, click the port and type in the new assignment. Port numbers must be unique and in the range of 1024 to 65535.

Note: If a PCx Docking Station is sharing the ethernet port with an i-STAT Downloader, the PCx port assignment is made in QC Manager.

Interface

The appropriate interface protocol and the types of records to be sent to another data management system are selected in the Interface tab page. This configuration will typically be done by the interface provider.

Select the desired primary interface protocol. Then select the result types to be sent to the interface.



☑ Enable external interface

☑ Enable AutoSend

Primary Interface Protocol
- ☐ [None]
- ☐ AME
- ☐ ASTM
- ☑ Data File
- ☐ HL7

Result Types to Send
- ☑ Test Result
- ☐ Electronic Simulator
- ☐ Control Result
- ☐ Cal/Ver Result
- ☐ Proficiency Result
- ☐ Other Results

☐ Upload PCx Strip Data to QC Manager 2.2

Primary Interface Protocol Choices	Explanation	Which Result Type(s) May be Transmitted
None	Indicates no primary protocol in use. Select when no external interface is used and PCx glucose test strip data is to be uploaded to QC Manager 3	N/A
AME	Automatic Manual Entry – Installed by Abbott Point of Care Inc.	1. Test Result 2. Electronic Simulator 3. Control Result 4. Cal/Ver Result 5. Proficiency Result
ASTM	Data Transmission conforms to ASTM E1381-95 and ASTM E1394-97	Patient Test Results ONLY
Data File	Formats the CDS for third-party use.	1. Test Result 2. Electronic Simulator 3. Control Result 4. Cal/Ver Result 5. Proficiency Result
HL7	Data transmission conforms to HL7 (version 2.4) and is based on the CIC Observation Reporting Interface distributed by the National Committee for Clinical Laboratory Science in the USA under Document POCT-1-A. This option is installed by Abbott Point of Care Inc.	Patient Test Results ONLY

Click **Enable external interface** box to check it and enable this function.

Click **Enable AutoSend** box to check it and enable this function. When AutoSend is enabled, new records will be automatically sent from the Central Data Station to another data management system whenever they are received by the Central Data Station. Checking this box will cause the CDS program to start up with AutoSend enabled on startup. AutoSend can be temporarily enabled/disabled from the CDS program as well. Records can also be sent manually from the Data Viewers.

When MediSense Precision PCx glucose test strips are being run on the i-STAT 1 Analyzer, the glucose test strip data can be made available to QC Manager data management program. Click the **Upload PCx Strip Data to QC Manager 2.2** box to enable this function.

Options

Confirmation message on exit: When this option is enabled, a confirmation message is displayed prior to exiting the CDS program.

Enable use of IR Link IDs: When enabled, the IDs programmed into the IR Links are used in determining the download location of the results instead of the actual serial port or IP address. To use this function, all IR Links must be of the self-identifying type. This option is not typically used but is available in case the functionality is needed.

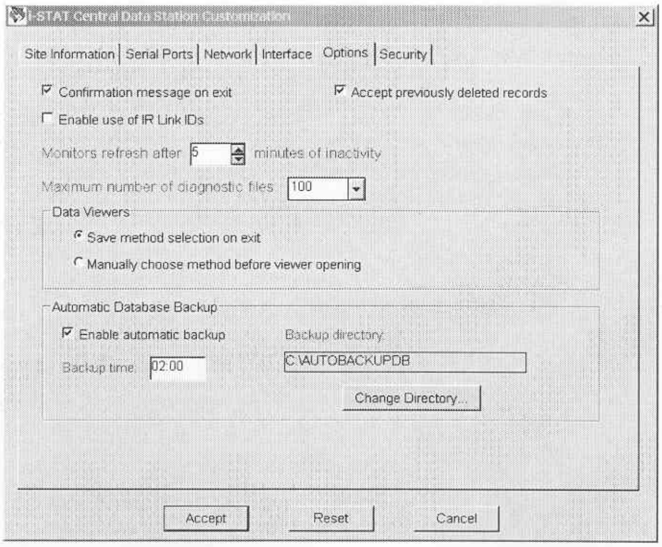
Accept previously deleted records: When disabled, this option prevents previously deleted records from being stored when re-transmitted to the Central Data Station.

Monitor refresh: The status reports in the Download and Interface Monitors will be updated after the period of inactivity specified.

Maximum diagnostic files: Diagnostic files contain information that can be useful in troubleshooting cartridge problems. The default number is 100 and is changed at the request of a Customer Support representative.

Data Viewers: Selecting **Save method selection on exit** will cause each Data Viewer to save whichever method was selected when the viewer is closed or the **Exit** button clicked. The next time the viewer or CDS software is opened, the saved method will be displayed. When **Manually choose method before viewer opening** is selected, the user will be prompted to choose a method before a data viewer is opened.

Automatic Database Backup: When enabled, the CDS database files will be backed up to the selected location at the time of day entered. Should there be a malfunction resulting in the corruption of the database, a Customer Support representative may be able to retrieve the lost data from the backup copy. Each backup replaces the previous one. Backup time depends on the size of the database but usually does not take longer than 15 minutes.



☑ Confirmation message on exit
☑ Accept previously deleted records
☐ Enable use of IR Link IDs
Monitors refresh after 5 minutes of inactivity
Maximum number of diagnostic files 100

Data Viewers
● Save method selection on exit
○ Manually choose method before viewer opening

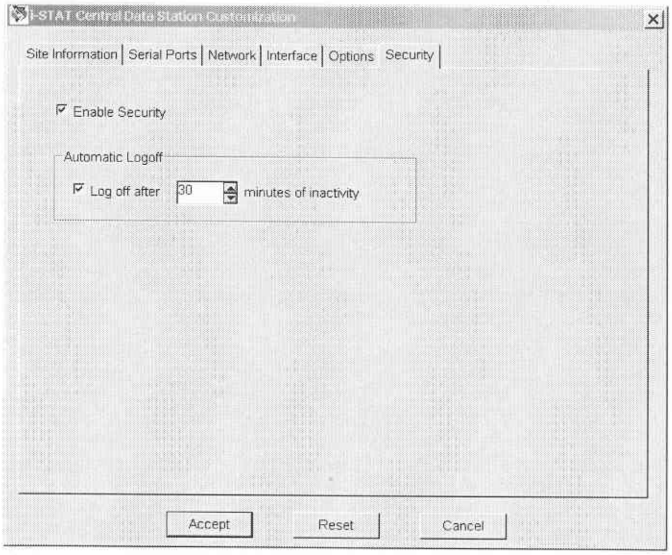
Automatic Database Backup
☑ Enable automatic backup
Backup time: 02:00
Backup directory: C:\AUTOBACKUPDB

Security

The security features allow for the creation of security profiles providing different levels of access to various areas and functions of the CDS application. Individual users can then be assigned to a security profile, and then choose their own individual CDS log-on password. The system also has capabilities for manual and automatic logoffs.

The security features should only be activated by the administrator of the System; i.e. the person ultimately in charge of the CDS who will be creating the security profiles and assigning users to them.

The security features can be activated by performing the following steps:



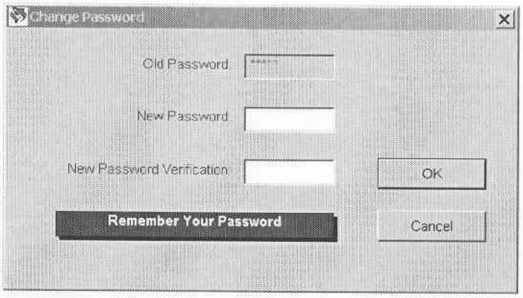
i-STAT Central Data Station Customization

☑ Enable Security

Automatic Logoff

☑ Log off after 30 minutes of inactivity

1. Check the box next to "Enable Security".
2. After enabling security, the user also has the option of selecting an inactivity interval after which the CDS will log off the current user. Simply click on the "Log Off" box and use the up/down arrows to choose the desired log off interval.
3. Click **Accept** at the bottom of the window.
4. A password dialog will then appear asking for a User Name and a Password. Type the User Name of **admin**, and the password **istat.** Then click on **OK**.
5. Another dialog box will appear prompting you to change your password.



Change Password

Old Password: *****

New Password:

New Password Verification:

6. Type in a New Password of your choosing in the space provided. Then retype that same password on the New Password Verification line and click **OK**. This will automatically bring you to the CDS application.

INTERFACE PROGRAM CUSTOMIZATION

Overview

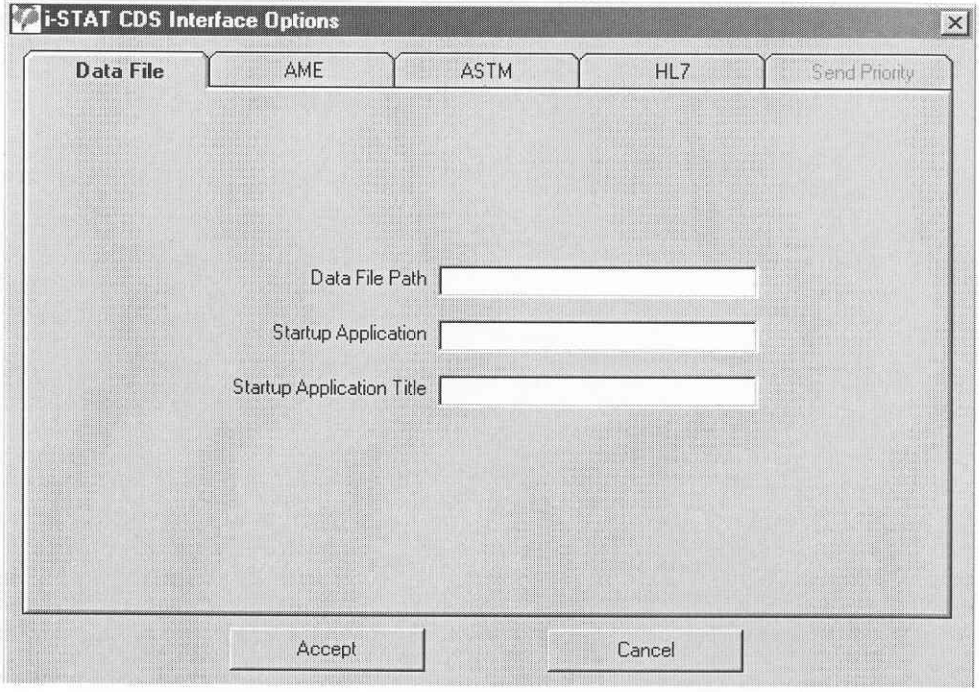
The Central Data Station can output results to an external computer system such as an LIS or HIS. The Central Data Station also provides a function that, when enabled, will also transmit all of the Precision PCx results generated on the i-STAT 1 Analyzer to QC Manager so they can be managed as part of the overall Blood Glucose Testing program.

The Central Data Station needs to be customized for the interface type using the procedures below. Tabs are presented for the options available. Each tab represents a protocol that the Interface Component of the CDS supports. Depending on the particular installation, one or more of these will be used.

Procedure

Exit the CDS application. Access the Run dialog box by clicking **Start ➪ Run...** Type **c:\istat32\bin\interface32.exe** at the **Open:** prompt, then click **OK**. If **Run...** is not on the Start menu, double click the **Command Prompt** shortcut. At the C:\> prompt in the window that opens, type **c:\istat32\bin\interface32.exe** and press **Enter**. Click **File ➪ Options**. The following screen will be displayed.

These tabs are used by the interface provider to configure the interface Component of the CDS for the protocol that will be used.

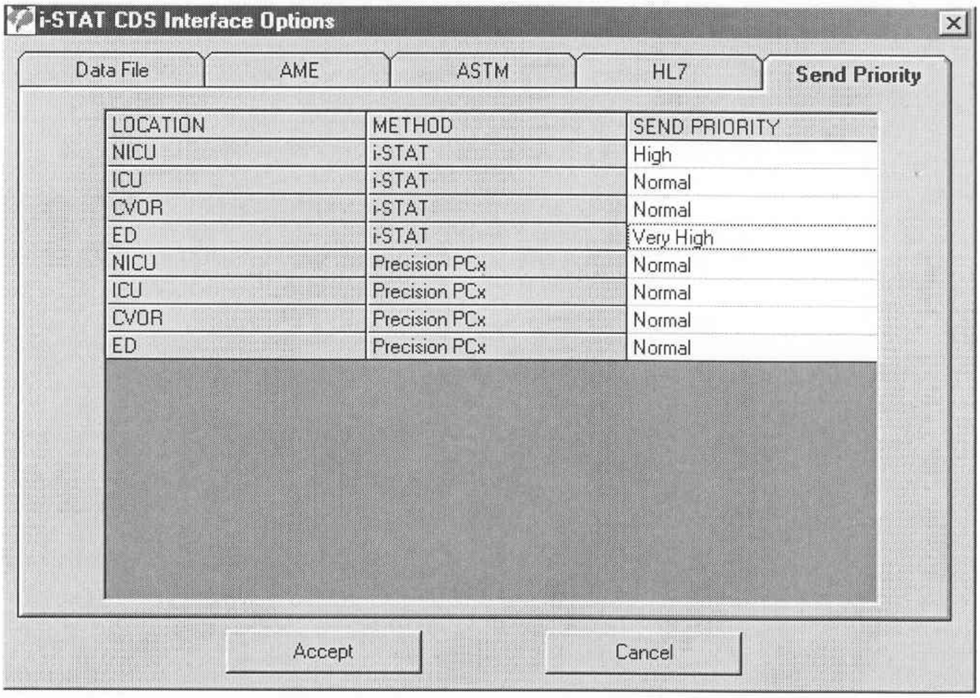


Send Priority

This function will prioritize the queue of results in the CDS database being processed by the Interface Component of the CDS program. This capability can be used by the interface provider to prioritize handling of results from one location over another.

Procedure

1. The CDS program must be running and the external interface must be enabled.
2. Double click the i-STAT interface icon in the system tray (next to the clock in the lower right hand corner of the screen) to open the interface program's main screen.
3. Click **File** ⇨ **Options**...
4. Click the **Send Priority** tab. (The other tabs will be available for viewing only.)
5. Click the Location/Method line to prioritize.
6. Right click under the **Send Priority** column and select the priority: Normal, High, Very High, from the drop down list.
7. Click **Accept** to finish.



LOCATION	METHOD	SEND PRIORITY
NICU	i-STAT	High
ICU	i-STAT	Normal
CVOR	i-STAT	Normal
ED	i-STAT	Very High
NICU	Precision PCx	Normal
ICU	Precision PCx	Normal
CVOR	Precision PCx	Normal
ED	Precision PCx	Normal

OVERVIEW OF THE CENTRAL DATA STATION PROGRAM

The Central Data Station (CDS) software includes the following point-of-care testing process management functions:

- Managing Instruments
- Managing Operators
- Managing Inventory
- Managing Policy Compliance
- Monitoring Operator Competence
- Reviewing Patient and Quality Results
- Managing Analyzer Customization Profiles
- Maintaining Database Contents and Size
- Monitoring External Interface Activities
- Monitoring Analyzer Download Intervals
- Managing LIS entry exceptions

These functions are listed under the main menu option in four main groupings: monitors, viewers, workspaces and reports.

Central Data Station Software Function Overview and Toolbar Buttons

- Monitor
  - Download
  - Interface
- Administration Tools (Workspaces)
  - Instrument/Location
  - Operator
  - Database Maintenance
  - Inventory
  - Customization
  - User Administration
- Data Viewer
  - Results (patient)
  - QC Codes
  - Simulator
  - Unsent Records
  - Control Results
  - Calibration Verification
  - Proficiency Tests
- Report
  - Reagent Management
  - Method Competence
  - Method Compliance

ADMINISTRATION TOOLS

Overview

Administration Tools include Workspaces for Instruments and Locations, Operators, Database Maintenance, Inventory, Customization, and User Administration.

INSTRUMENT AND LOCATION WORKSPACE

Overview

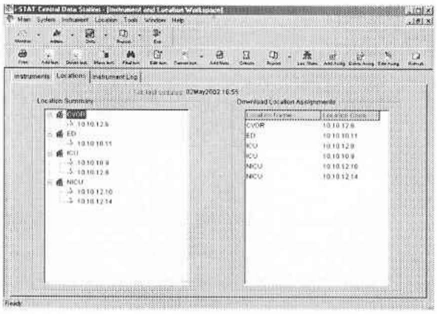
This workspace is used to:

- assign names to download locations,
- assign instruments to locations,
- configure the reporting and monitoring options for each instrument, and
- set required download intervals for each location.

The following sequence of tasks is used to set up the Central Data Station's management function for instruments:

1. Assign Location Names to Location Codes. Location Codes are the physical port addresses for the download devices.
2. Assign Instruments to Download Locations.

Locations


STAT Central Data Station - [Instrument and Location Workspace]
Main
System
Instrument
Location
Tools
Window
Help
Instruments
Locations
Instrument Log
Location Summary
Download Location Assignments
Ready

☐ Edit Location Name

The location name can be changed from a letter/number code to the name of a nursing unit, department, site, etc.. Up to 17 characters can be used to identify a location. Click **Location ➪ Edit Location Name...** in the menu or click **Loc. Name** in the toolbar.

Note: Interface logic should be considered before editing.

☐ Add New Download Location Assignment

Download locations can be added manually. Click **Location ➪ Add Download Location Assignment...** in the menu or click the **Add Assig.** in the toolbar. Download locations will also be added automatically when a transmission is received from a download device with a location that is not already on the list. The name assigned is A_xx, where xx is the download device's IP address or serial port. This name can be changed as described under **Edit Download Location Assignment**.

To assign instruments to a location without a download device, enter a Location Name or another descriptive word as the Location Code.

☐ Delete Download Location Assignment

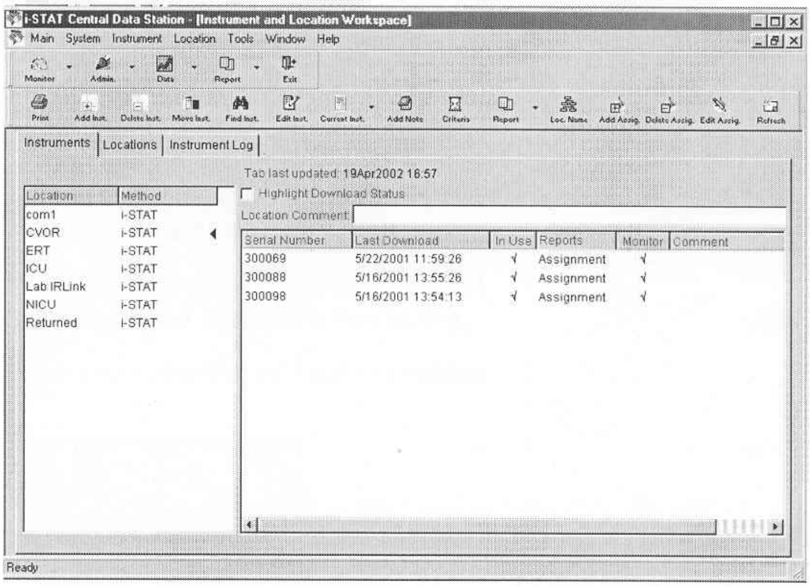
Click **Location ➪ Delete Download Location Assignment...** from the menu or click **Delete Assig.** in the toolbar.

☐ Edit Download Location Assignment

Click **Location ➪ Edit Download Location Assignment...** from the menu or click **Edit Assig.** in the toolbar.

Instruments

Once physical download locations have been given location names, the Instruments tab page will be the focus of management activities.


i-STAT Central Data Station - [Instrument and Location Workspace]
Main
System
Instrument
Location
Tools
Window
Help
Monitor
Admin.
Data
Report
Exit
Print
Add Inst.
Delete Inst.
Move Inst.
Find Inst.
Edit Inst.
Current Inst.
Add Note
Criteria
Report
Loc. Name
Add Assig.
Delete Assig.
Edit Assig.
Refresh
Instruments
Locations
Instrument Log
Ready

Tab last updated: 19Apr2002 16:57

☐ Highlight Download Status

Location Comment:

Location	Method	
com1	i-STAT	
CVOR	i-STAT	◀
ERT	i-STAT	
ICU	i-STAT	
Lab IRLink	i-STAT	
NICU	i-STAT	
Returned	i-STAT	

Serial Number	Last Download	In Use	Reports	Monitor	Comment
300069	5/22/2001 11:59:26	√	Assignment	√	
300088	5/16/2001 13:55:26	√	Assignment	√	
300098	5/16/2001 13:54:13	√	Assignment	√	

Location: Instruments are assigned to locations. This assignment is made when an instrument is manually added in the Instruments page or when an instrument downloads to the Central Data Station for the first time.

Method: The CDS is designed to accept results from any instrument that can be downloaded to the CDS program. The i-STAT method in the Instrument window refers to the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer (both i-STAT cartridge and MediSense Precision PCx and PCx Plus Glucose Test Strips) and the Philips Blood Analysis Module.

Clicking a Location/Method on the left side of the window will list the status of all instruments for that location and method in the right side of the window. A ◀ symbol indicates which location and method has been selected.

Highlight Download Status: Checking this box will highlight locations with instruments that have exceeded the required interval for downloading as well as noncompliant instruments within the location selected.

☐ Add Instrument

The Add instruments window is used to add an instrument to the system. Click **Instrument ➪ Add...** from the menu or click **Add Inst.** in the toolbar. Select a method from the drop down list.

Note: If using the i-STAT 1 Analyzer for cartridge and/or test strip runs, select i-STAT as the method.

Select a location from the dropdown list. If the location is not listed, add the location using the instructions under Add New Download Location Assigment. If the location does not have a download device associated with it, such as an instrument used for transporting patients, a location name can be typed in. (In this case the Location Code on the Locations tab page will be SYSCODExxxxxx.) Up to 17 characters can be used.

There are two options for Download Result Reporting, both of which apply to the i-STAT PCA, i-STAT 1 Analyzer, and the Philips Blood Analysis Module:

1. **Always report location as this assignment:** The results from this instrument will appear with the location of the instrument's assignment regardless of the download device used to transmit the results. This option is useful when an instrument is assigned to a functional group that may download from various areas in the institution. The instrument will be designated "Assignment" under the Reports column in the Instruments tab page.

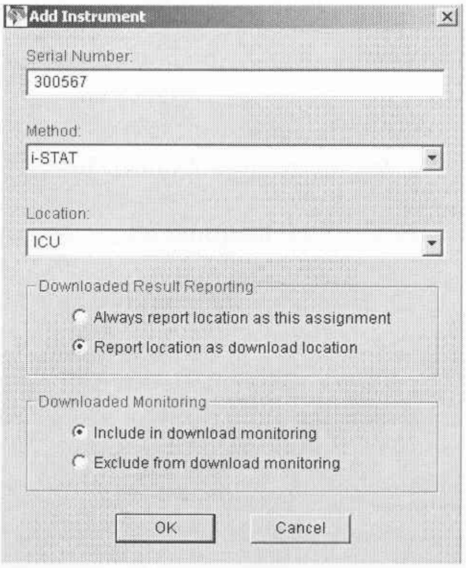
2. **Report location as download location:** The results from this instrument will appear with the location for the download device that was used to transmit results to the Central Data Station. The instrument will be designated "Download" under the Reports column on the Instruments tab page.

   If the instrument is not manually added to the list and it transmits to the CDS, it is automatically assigned to the location of the download device and is set to report "Download." If the download device location has not been manually added, a default location A_xx (B_xx, C_xx, etc.), where xx is the IP address or serial port of the download device, will be used.

There are two options for Download monitoring:

1. **Include in download monitoring:** Includes this Serial Number in download monitoring.

2. **Exclude download monitoring:** The download status of the instrument will not be reported by the Download Monitor. (Blood Analysis Modules and infrequently used or spare analyzers might be exempted from the Download Monitor report).



Serial Number: 300567

Method: i-STAT

Location: ICU

Downloaded Result Reporting

○ Always report location as this assignment

● Report location as download location

Downloaded Monitoring

● Include in download monitoring

○ Exclude from download monitoring

☐ Delete Instrument

Click the Location/Method for the instrument to be deleted and then the serial number of the instrument to be deleted. Click **Instrument ➪ Delete...** from the menu or click **Delete Inst.** in the toolbar.

☐ Move Instrument

Click the Location/Method for the instrument to be moved and then on the serial number of the instrument to be moved. Click **Instrument ➪ Move...** from the menu or click **Move Inst.** in the toolbar. Select the new location from the drop down list or type in a new location.

☐ Find Instrument

Click **Instrument ➪ Find...** from the menu or click **Find...** in the toolbar. Enter the serial number of the instrument and select the Method from the drop down list.

☐ Edit Instrument Comment

Click the instrument serial number, click **Instrument ➪ Edit Comment** from the menu or click **Edit Inst.** in the toolbar. Enter a comment of up to 16 characters.

☐ Change Current Instrument Setttings

Reporting: Click the instrument serial number. Click **Instrument ➪ Current Instrument ➪ Change Reporting** from the menu or click the down arrow next to **Current Inst.** and then **Reporting** in the toolbar to toggle between **Download** and **Assignment**.

In Use: Click the instrument serial number. Click **Instrument ➪ Current Instrument ➪ Toggle In Use** from the menu or click the down arrow next to **Current Inst.** and then **In Use** in the toolbar to check (in use) or un-check (out of use) the analyzer in the In Use column.

Instruments that are not checked “In Use” do not have a download criteria applied to them. You would use this for instruments you do not expect to be downloaded. When an analyzer that is not marked “in use” downloads, it is set back in use and the download criteria is applied.

Monitoring: Click the instrument serial number. Click **Instrument ➪ Current Instrument ➪ Change Monitoring** from the menu or click the down arrow next to **Current Inst.** and then **Monitoring** in the toolbar to check or un-check the analyzer in the Monitoring column.

☐ Add Instrument Note

Click **Instrument ➪ Add Note...** from the menu or click **Add Note** in the toolbar. A note of up to 50 characters can be entered. The note will appear as a Log Entry in the Instrument Log tab page.

☐ Change Download Monitoring Criteria

Compliance to download policy can be monitored by the CDS program. Click on the Location/Method. Click on **Instrument ➪ Download Criteria...** from the menu or click **Criteria** in the toolbar. Enter the required download interval. An interval of up to 1000 hours is allowed.

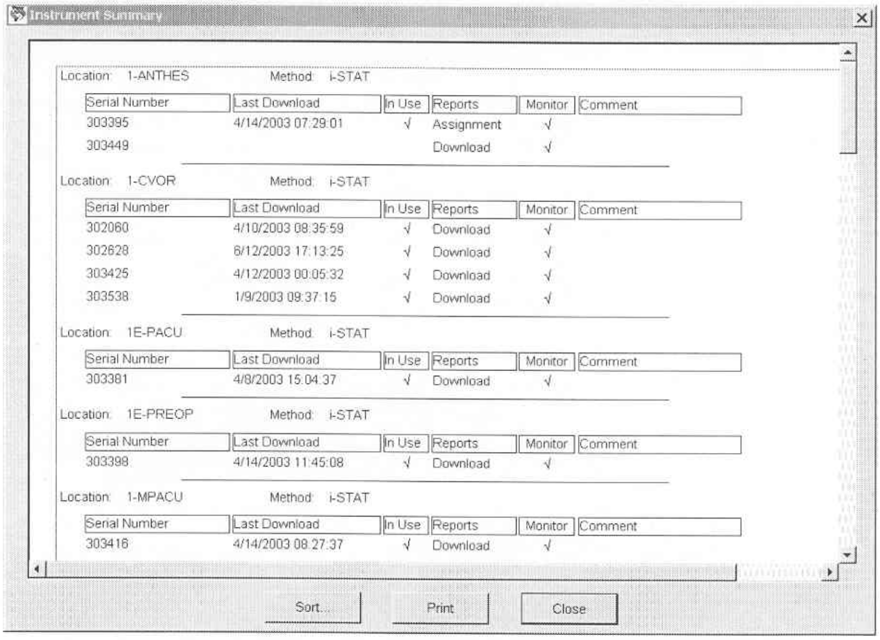
Compliance with the criteria can be observed by checking the Highlight Download Status check box or by going to the Download Monitor. Individual Download criteria can be set for each location and method pair.

Note: The i-STAT 1 Analyzer can also be customized either to warn the end users that a download is required or to lockout end users if the time for a download has been reached or exceeded. The download criteria for analyzers and for the CDS monitor should be selected to make sense.

❑ Instrument and Location Summary

The Instrument and Location Summary provides a report of the current instrument assignments and the last download for each instrument. Click **Main ➪ Open Report ➪ Instrument Summary** from the menu or click the down arrow next to **Report** and then **Summary** in the toolbar. Summaries can be viewed and printed by:

- This method and location only (location and method selected with ◄ symbol)
- This method, all locations (method selected with ◄ symbol)
- All methods, all locations



Location: 1-ANTHES Method: i-STAT

Serial Number	Last Download	In Use	Reports	Monitor	Comment
303395	4/14/2003 07:29:01	√	Assignment	√	
303449			Download	√	

Location: 1-CVOR Method: i-STAT

Serial Number	Last Download	In Use	Reports	Monitor	Comment
302060	4/10/2003 08:35:59	√	Download	√	
302628	6/12/2003 17:13:25	√	Download	√	
303425	4/12/2003 00:05:32	√	Download	√	
303538	1/9/2003 09:37:15	√	Download	√	

Location: 1E-PACU Method: i-STAT

Serial Number	Last Download	In Use	Reports	Monitor	Comment
303381	4/8/2003 15:04:37	√	Download	√	

Location: 1E-PREOP Method: i-STAT

Serial Number	Last Download	In Use	Reports	Monitor	Comment
303398	4/14/2003 11:45:08	√	Download	√	

Location: 1-MPACU Method: i-STAT

Serial Number	Last Download	In Use	Reports	Monitor	Comment
303416	4/14/2003 08:27:37	√	Download	√	

Instrument Log

The Instrument Log tracks all changes made in the Instruments tab page. Additional comments can be added to the log by clicking **Add Note** in the toolbar.

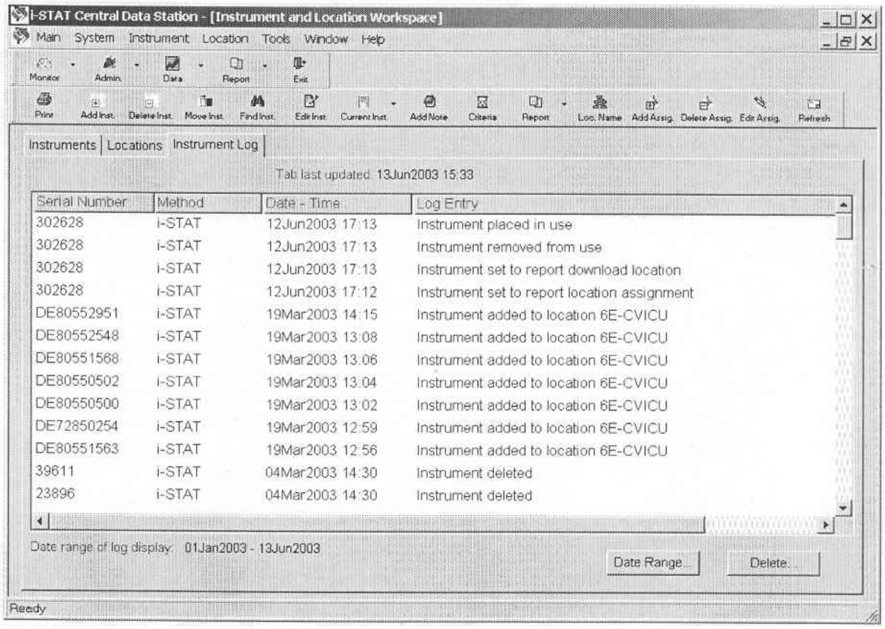
☐ Date Range...

Data can be viewed within a user defined default range or by a manually entered range.

☐ Delete...

The **Delete** button allows selected or all entries within the date range selected to be deleted.

To print the log press the **F2** key or select **Print** from the Main menu or toolbar.


i-STAT Central Data Station - [Instrument and Location Workspace]
Main System Instrument Location Tools Window Help
Monitor Admin. Data Report Exit
Print Add Inst. Delete Inst. Move Inst. Find Inst. Edit Inst. Current Inst. Add Note Criteria Report Loc. Name Add Assig. Delete Assig. Edit Assig. Refresh
Instruments Locations Instrument Log
Date Range... Delete...
Ready

Tab last updated: 13Jun2003 15:33

Serial Number	Method	Date - Time	Log Entry
302628	i-STAT	12Jun2003 17:13	Instrument placed in use
302628	i-STAT	12Jun2003 17:13	Instrument removed from use
302628	i-STAT	12Jun2003 17:13	Instrument set to report download location
302628	i-STAT	12Jun2003 17:12	Instrument set to report location assignment
DE80552951	i-STAT	19Mar2003 14:15	Instrument added to location 6E-CVICU
DE80552548	i-STAT	19Mar2003 13:08	Instrument added to location 6E-CVICU
DE80551568	i-STAT	19Mar2003 13:06	Instrument added to location 6E-CVICU
DE80550502	i-STAT	19Mar2003 13:04	Instrument added to location 6E-CVICU
DE80550500	i-STAT	19Mar2003 13:02	Instrument added to location 6E-CVICU
DE72850254	i-STAT	19Mar2003 12:59	Instrument added to location 6E-CVICU
DE80551563	i-STAT	19Mar2003 12:56	Instrument added to location 6E-CVICU
39611	i-STAT	04Mar2003 14:30	Instrument deleted
23896	i-STAT	04Mar2003 14:30	Instrument deleted

Date range of log display: 01Jan2003 - 13Jun2003

OPERATOR WORKSPACE

Overview

This workspace is used to:

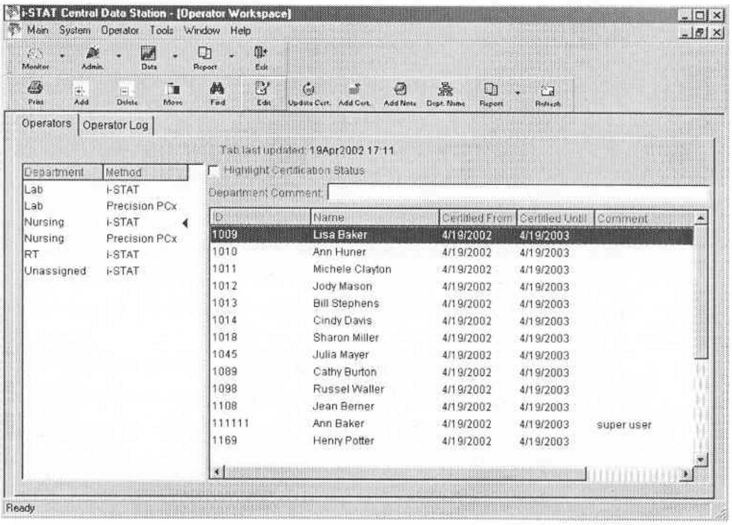
- Record operator names and identification numbers
- Record certification dates and certification expiration dates
- Assign operators to departments
- Add comments

When the i-STAT 1 Analyzer is customized to use the operator list created here, the analyzer can be customized to warn or lockout operators if they are not on the list or their certification has expired.

Operators

Operators are listed by Department and Method as indicated by the ◀ symbol. Operators are added to the operator list by department and by method.

When a record is received with an Operator ID that is not listed in any Department, the operator is placed in the "Unassigned" department.


i-STAT Central Data Station - [Operator Workspace]
Main System Operator Tools Window Help
Monitor
Admin.
Data
Report
Exit
Print
Add
Delete
Move
Find
Edit
Update Cert.
Add Cert.
Add Note
Dept. Name
Report
Refresh
Operators
Operator Log
Ready

Tab last updated: 19Apr2002 17:11

☐ Highlight Certification Status

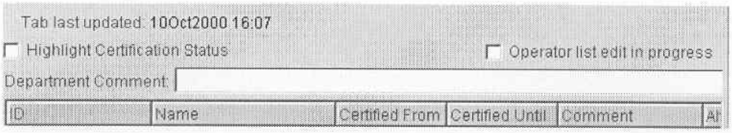
Department Comment:

Department	Method	
Lab	i-STAT	
Lab	Precision PCx	
Nursing	i-STAT	◀
Nursing	Precision PCx	
RT	i-STAT	
Unassigned	i-STAT	

ID	Name	Certified From	Certified Until	Comment
1009	Lisa Baker	4/19/2002	4/19/2003	
1010	Ann Huner	4/19/2002	4/19/2003	
1011	Michele Clayton	4/19/2002	4/19/2003	
1012	Jody Mason	4/19/2002	4/19/2003	
1013	Bill Stephens	4/19/2002	4/19/2003	
1014	Cindy Davis	4/19/2002	4/19/2003	
1018	Sharon Miller	4/19/2002	4/19/2003	
1045	Julia Mayer	4/19/2002	4/19/2003	
1089	Cathy Burton	4/19/2002	4/19/2003	
1098	Russel Waller	4/19/2002	4/19/2003	
1108	Jean Berner	4/19/2002	4/19/2003	
111111	Ann Baker	4/19/2002	4/19/2003	super user
1169	Henry Potter	4/19/2002	4/19/2003	

☐ Operator list edit in progress

When editing the operator list, check this box to delay updating i-STAT 1 analyzers until all editing is complete. When editing is complete, click the box to remove the checkmark. This box will appear when Serial or Network Communications are enabled, Customization is enabled and Use Operator List is enabled.



Tab last updated: 10Oct2000 16:07

☐ Highlight Certification Status

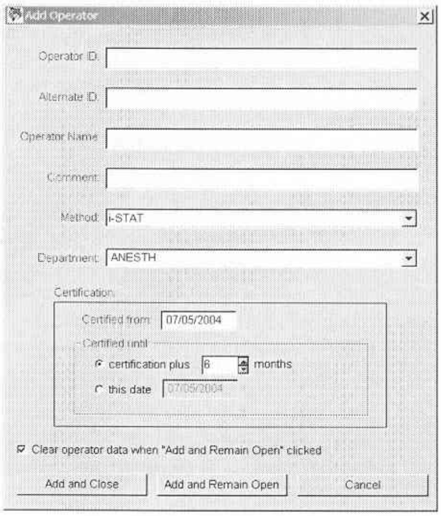
☐ Operator list edit in progress

Department Comment:

ID	Name	Certified From	Certified Until	Comment	Al

☐ Add Operator

This function is used to add new operators to the list of operators. Alternatively, operator lists can be imported (see Operator List Import at the end of this section). Click **Operator ➪ Add**... from menu or **Click** on **Add** in the toolbar.



Method: i-STAT

Department: ANESTH

Certified from: 07/05/2004

● certification plus 6 months

○ this date 07/05/2004

☑ Clear operator data when "Add and Remain Open" clicked

Enter the ID number that the operator will enter into the analyzer on the Operator ID line. If a different ID number is used to access the LIS, this number should be recorded on the Alternate ID line. An Operator Name of up to 40 characters can be entered. A comment of up to 16 character can be added. If operators are to be certified for more than one method, such as for the i-STAT cartridge and the PCx glucose test strip, certify each operator for one method and use the **Add Cert.** toolbar button to certify all applicable operators at one time for the method. To add the first operator to a department, type the department name (up to 10 characters). Once a department has been added, it can be selected for additional operators from the drop down menu.

Check the **Clear Operator data when "Add and Remain Open" clicked** box to specify whether or not the operator information fields should be cleared when the Add and Remain open button's clicked.

☐ Delete Operator

Select the operator or operators. Click **Operator ➪ Delete...** from the menu or click **Delete** in the toolbar to delete the operator or operators. When the last operator from a department is deleted, the department is removed from the system.

☐ Move Operator

Select the operator or operators. Click **Operator ➪ Move...** from the menu or click **Move** in the toolbar, and select a new department from the drop down list. If the department is not in the list, type in the new department name.

☐ Find Operator

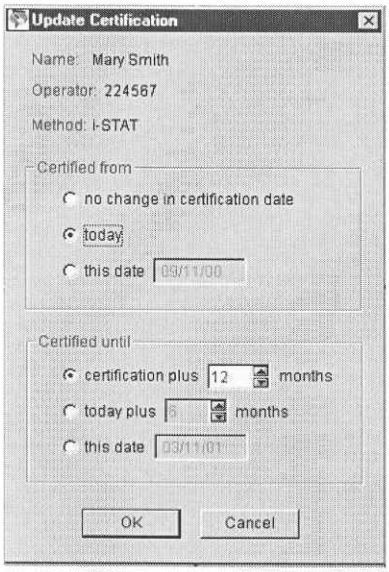
Click **Operator ➪ Find...** from the menu or click **Find** in the toolbar, select the method for which the operator is certified, and type in the operator ID. A box will appear around the found operator.

☐ Edit Operator Data

Click the operator. Click **Operator ➪ Edit** from the menu or click **Edit** in the toolbar. The operator ID, name, comment and alternate ID can be edited.

☐ Update Certifications

Select the operator or operators. Click **Operator ➪ Update Certification...** from the menu or click **Update Cert.** in the toolbar and complete the Update Certification form.



Update Certification

Name: Mary Smith

Operator: 224567

Method: i-STAT

Certified from

○ no change in certification date

● today

○ this date 09/11/00

Certified until

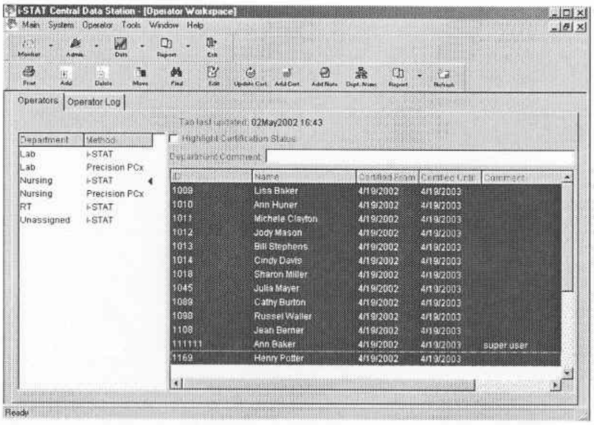
● certification plus 12 months

○ today plus 6 months

○ this date 03/11/01

☐ Add Certification

The Add Certification button allows operators who are certified for one method to be certified for another method without having to complete a new Add Operator form. Highlight the operator or operators in the Operator tab window that are to be certified for another method. Click **Operator ➪ Add Certification...** from the menu or click the **Add Cert.** button on the toolbar. Select the other method for which these operators are to be certified, then specify the certification dates.



i-STAT Central Data Station - [Operator Workspace]

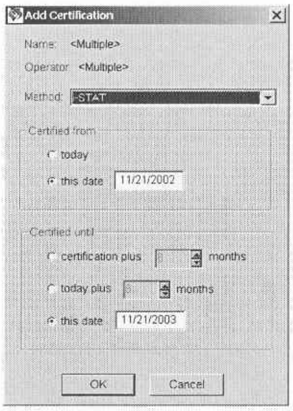
Tab last updated: 02May2002 16:43

☐ Highlight Certification Status

Department Comment:

Department	Method
Lab	i-STAT
Lab	Precision PCx
Nursing	i-STAT
Nursing	Precision PCx
RT	i-STAT
Unassigned	i-STAT

ID	Name	Certified From	Certified Until	Comment
1009	Lisa Baker	4/19/2002	4/19/2003	
1010	Ann Huner	4/19/2002	4/19/2003	
1011	Michele Clayton	4/19/2002	4/19/2003	
1012	Jody Mason	4/19/2002	4/19/2003	
1013	Bill Stephens	4/19/2002	4/19/2003	
1014	Cindy Davis	4/19/2002	4/19/2003	
1018	Sharon Miller	4/19/2002	4/19/2003	
1045	Julia Mayer	4/19/2002	4/19/2003	
1089	Cathy Burton	4/19/2002	4/19/2003	
1098	Russel Waller	4/19/2002	4/19/2003	
1108	Jean Berner	4/19/2002	4/19/2003	
111111	Ann Baker	4/19/2002	4/19/2003	super user
1169	Henry Potter	4/19/2002	4/19/2003	



Add Certification

Name: <Multiple>

Operator: <Multiple>

Method: i-STAT

Certified from

○ today

● this date 11/21/2002

Certified until

○ certification plus months

○ today plus 6 months

● this date 11/21/2003

☐ Add Note

Click the operator. Click **Operator ➪ Add Note...** from the menu or click **Add Note** in the toolbar. An Operator Log Note of up to 50 characters can be typed.

☐ Edit Department Name

Click the department name to edit. Click **Operator ➪ Edit Department Name** from the menu or click **Dept. Name** in the toolbar. The Unassigned designation cannot be changed.

☐ Operator and Certification Reports

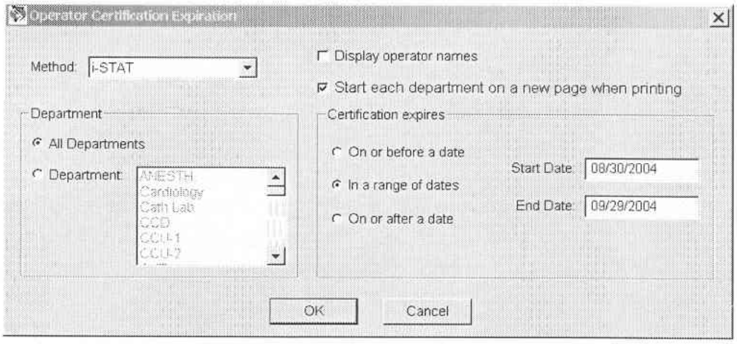
Click on the down arrow next to **Report** in the Operator Workspace toolbar and click on **Summary** or **Expiration**.

Operator Summary: Summaries of operators can be viewed and printed by:

- This method and department only (department and method selected with ◀ symbol)
- This method, all departments (method selected with ◀ symbol)
- All methods, all departments

  The reports include operator IDs, operator names, certified from date, certified until date, comments, a checkmark if certification has expired and the operator's alternate IDs grouped by department and method.

Operator Certification Expiration: This report allows the certification status of operators to be viewed.



Method: i-STAT

☐ Display operator names

☑ Start each department on a new page when printing

Department

● All Departments

○ Department: ANESTH, Cardiology, Cath Lab, CCD, CCU-1, CCU-2

Certification expires

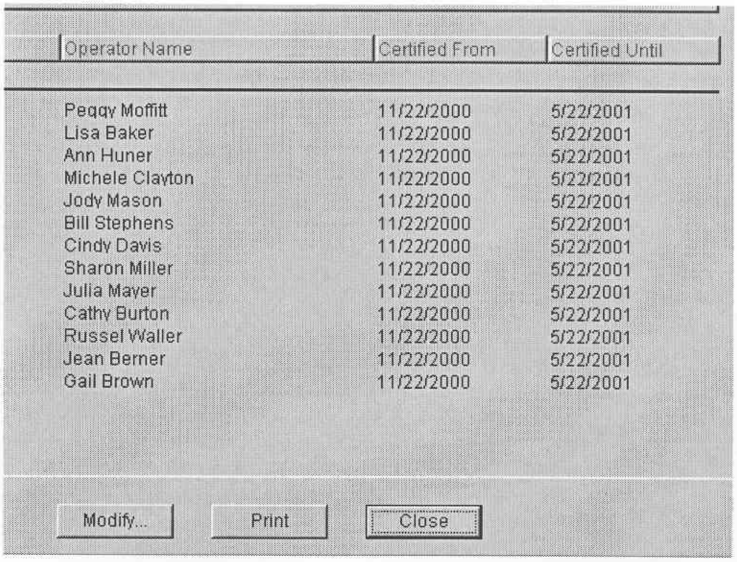
○ On or before a date

● In a range of dates

○ On or after a date

Start Date: 08/30/2004

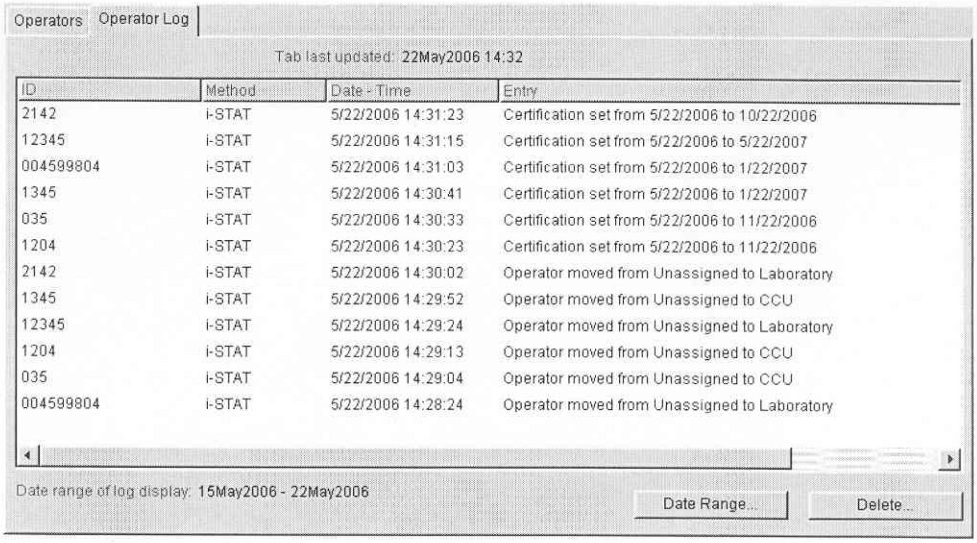
End Date: 09/29/2004



Operator Name	Certified From	Certified Until
Peggy Moffitt	11/22/2000	5/22/2001
Lisa Baker	11/22/2000	5/22/2001
Ann Huner	11/22/2000	5/22/2001
Michele Clayton	11/22/2000	5/22/2001
Jody Mason	11/22/2000	5/22/2001
Bill Stephens	11/22/2000	5/22/2001
Cindy Davis	11/22/2000	5/22/2001
Sharon Miller	11/22/2000	5/22/2001
Julia Mayer	11/22/2000	5/22/2001
Cathy Burton	11/22/2000	5/22/2001
Russel Waller	11/22/2000	5/22/2001
Jean Berner	11/22/2000	5/22/2001
Gail Brown	11/22/2000	5/22/2001

Operator Log

The Operator Log tracks changes made and "Add Note" entries made in the Operator tab page. The **Date Range...** button can be used to specify a time period to be viewed and the **Delete...** button to delete entries. To print the log press the **F2** key or select **Print** from the Main menu.



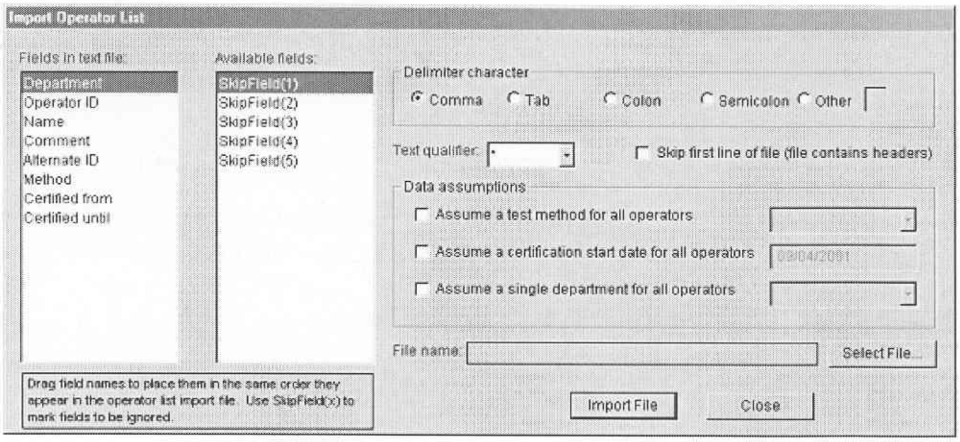
Tab last updated: 22May2006 14:32

ID	Method	Date - Time	Entry
2142	i-STAT	5/22/2006 14:31:23	Certification set from 5/22/2006 to 10/22/2006
12345	i-STAT	5/22/2006 14:31:15	Certification set from 5/22/2006 to 5/22/2007
004599804	i-STAT	5/22/2006 14:31:03	Certification set from 5/22/2006 to 1/22/2007
1345	i-STAT	5/22/2006 14:30:41	Certification set from 5/22/2006 to 1/22/2007
035	i-STAT	5/22/2006 14:30:33	Certification set from 5/22/2006 to 11/22/2006
1204	i-STAT	5/22/2006 14:30:23	Certification set from 5/22/2006 to 11/22/2006
2142	i-STAT	5/22/2006 14:30:02	Operator moved from Unassigned to Laboratory
1345	i-STAT	5/22/2006 14:29:52	Operator moved from Unassigned to CCU
12345	i-STAT	5/22/2006 14:29:24	Operator moved from Unassigned to Laboratory
1204	i-STAT	5/22/2006 14:29:13	Operator moved from Unassigned to CCU
035	i-STAT	5/22/2006 14:29:04	Operator moved from Unassigned to CCU
004599804	i-STAT	5/22/2006 14:28:24	Operator moved from Unassigned to Laboratory

Date range of log display: 15May2006 - 22May2006

OPERATOR LIST IMPORT

This function in the Operator Workspace on the CDS5 allows an operator list to be imported from a text file. To access this function, click on **Main ➪ Open Administration Function ➪ Operator** from the main menu to open the Operator Workspace. Select **Operator ➪ Import List...** from the main menu to open the Import Operator List window. This window is used to describe the format of the text file containing the list to be imported into the CDS.



Import Operator List

Fields in text file:

Department
Operator ID
Name
Comment
Alternate ID
Method
Certified from
Certified until

Available fields:

SkipField(1)
SkipField(2)
SkipField(3)
SkipField(4)
SkipField(5)

Delimiter character

● Comma ○ Tab ○ Colon ○ Semicolon ○ Other

Text qualifier: "

☐ Skip first line of file (file contains headers)

Data assumptions

☐ Assume a test method for all operators

☐ Assume a certification start date for all operators 08/04/2001

☐ Assume a single department for all operators

File name:

Drag field names to place them in the same order they appear in the operator list import file. Use SkipField(x) to mark fields to be ignored.

Import List Instructions

1. Under **Fields in text file:**, use the mouse to drag and drop the field names so they match the order in which the fields appear in the text file containing the list to be imported. If a field does not appear in the text file, drag it to the **Available fields**: list. If the text file contains a field that should be ignored, drag a **SkipField(x)** field to the **Fields in text file:** list to mark where that field appears.

2. Fields in the text file containing the list to be imported must be separated by a comma or other delimiter character. Specify the separator in the **Delimiter character** box.

3. If a qualifier character is used to enclose the data contained in each the field in the text file containing the list to be imported, select this character from the **Text qualifier:** list.

4. If the first line of the text file is a header line listing the names of the fields in the text file containing the list to be imported, click **Skip first line of file (file contains headers)**. The import function cannot process header lines.

5. If all operators in the text file containing the list to be imported are to be certified for one method, click **Assume a test method for all operators** and select **i-STAT** for cartridge testing or **Precision PCx** for the MediSense Precision PCx or PCx Plus Glucose Strip testing on the i-STAT1 Analyzer. If this option is selected, the text file does not need to contain a **Method** field. If this option is selected and the text file does contain a **Method** field, its contents will be ignored

6. If all operators will be certified from the same date, click on **Assume a certification start date for all operators** and enter the start date. If this option is selected, the text file does not need to contain a **Certified from** field. If this option is selected and the text file does contain a **Certified from** field, its contents will be ignored.

7. If all operators are to be assigned to the same department, such as Nursing or Perfusion, click on **Assume a single department for all operators** and enter or select the department from the drop down list. If this option is selected, the text file does not need to contain a **Department** field. If this option is selected and the text file does contain a **Department** field, its contents will be ignored

   Example from list to be imported:

   "ICU", "12345", "Smith, Judy", "none", "98765", "i-STAT", "2001-08-08", "2002-08-08"

8. Click **Select File...** and select the name of text file containing the list to be imported.

9. Click **Import File** to import the list from the text file.

Note: operator data that already exits in the CDS5 database takes precedence over any data imported from a text file.

Export List

After a list has been imported or created, it can be exported for backup purposes.

DATABASE MAINTENANCE

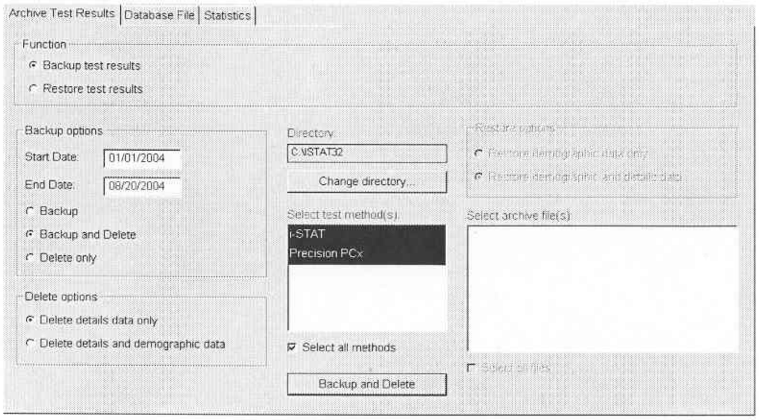
Overview

This workspace allows the database to be backed up, deleted and restored. A "Statistics" tab page also allows users to view a summary page of Result Types contained in the database.

Archive Test Results

Backup test results: This function allows test results to be backed up onto a disk, CD or other directory. (Note: a 1.44MB disk will only store about 1000 test records.)

1. Click on **Main** ➪ **Open Administration Functions** ➪ **Database Maintenance.**
2. After the workspace opens, click the **Archive Test Results** tab.


Archive Test Results
Database File
Statistics
Function
Backup options
Delete options
Restore options
Change directory...
Backup and Delete
Select archive file(s):
○ Restore demographic data only
● Restore demographic and details data
☐ Select all files

● Backup test results
○ Restore test results

Start Date: 01/01/2004
End Date: 08/20/2004
○ Backup
● Backup and Delete
○ Delete only

● Delete details data only
○ Delete details and demographic data

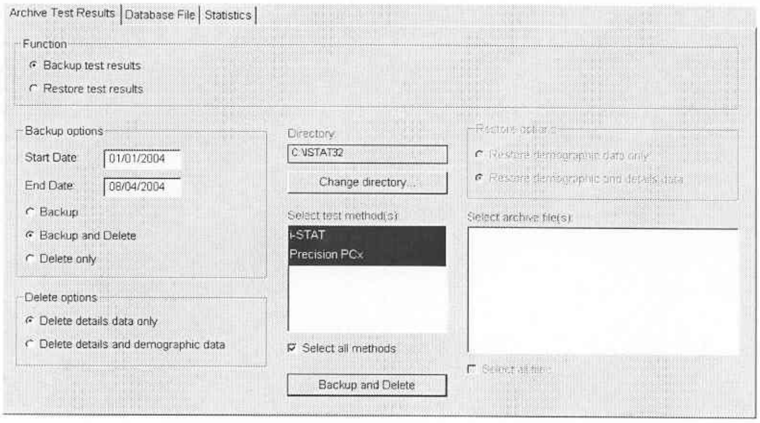
Directory: C:\ISTAT32
Select test method(s): i-STAT, Precision PCx
☑ Select all methods

3. Click the **Backup** test results radio button.
4. Specify a date range for the function.
5. Select a Backup Option: **Backup**, **Backup and Delete**, or **Delete only.**
6. If an option that includes Delete is selected, then select a Delete Option: **Delete details data only** or **Delete details and demographic data**. Details data includes:
   - Original Operator and Patient ID
   - Patient Name
   - LIS order number
   - Sent status
   - Analyte values
   - Extra data

   Demographic data can be used to generate reports. Demographic data includes:
   - Test type (test result, simulator, proficiency,...)
   - Test panel (such as EC8$^+$, CG8$^+$, PCx Glucose)
   - Test Method (i-STAT, Precision PCx...)
   - Patient ID
   - Operator ID
   - Test date/time

- Location
- Comment
- Interface comment
- Serial number
- Department

7. Select a Directory.
8. Select a method or methods to back up or click **Select all methods.**



Archive Test Results | Database File | Statistics

Function
- ● Backup test results
- ○ Restore test results

Backup options
- Start Date: 01/01/2004
- End Date: 08/04/2004
- ○ Backup
- ● Backup and Delete
- ○ Delete only

Delete options
- ● Delete details data only
- ○ Delete details and demographic data

Directory: C:\ISTAT32

Change directory...

Select test method(s):
- i-STAT
- Precision PCx

☑ Select all methods

Backup and Delete

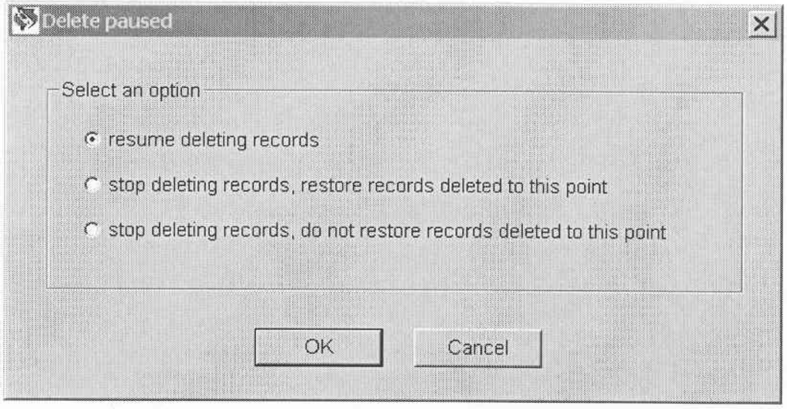
Restore options
- ○ Restore demographic data only
- ● Restore demographic and details data

Select archive file(s):

☐ Select all files

9. Click the button marked **Backup** or **Backup and Delete** and follow the prompts.

Note: When results are being deleted as part of a backup and delete or a delete only operation, the deletion can be cancelled. Simply click on the **Cancel** button to stop the operation. Once the **Cancel** button is clicked, depending on the amount of data being deleted and the size of the database, there may be a significant lag time of a few minutes before a dialog box appears indicating that the deletion has been paused, asking you to select one of three options:



Delete paused

Select an option
- ● resume deleting records
- ○ stop deleting records, restore records deleted to this point
- ○ stop deleting records, do not restore records deleted to this point

OK | Cancel

The reason for the lag time is that the program needs to complete whatever portion of the deletion operation it was performing when the **Cancel** button was clicked before it can display the dialog box. Once the dialog box is displayed, simply click on the desired radio button and then click **OK**.

Restore test results: This function allows test results that have been deleted from the CDS but backed up elsewhere to be restored to the database.

1. Click on **Main ➪ Open Administration Functions ➪ Database Maintenance.**
2. Insert disk or CD where files are located.
3. Click the **Restore test results** radio button.
4. Select the directory for the stored results.
5. Select the method or methods to be restored.
6. Select a restore option: **Restore demographic data only** or **Restore demographic and details data.** (Demographic data can be used to generate reports.)
7. Select the files to be restored or select all files.
8. Click the **Restore** button.

Database File

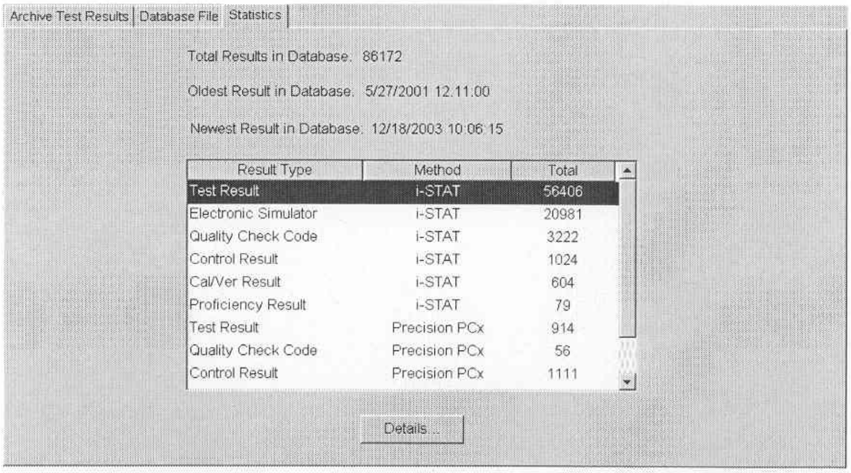
Backup Database File: This function allows the user to manually perform the same operation that occurs when the automatic database backup occurs. It creates a complete backup of the database file to the specified drive/directory.

Compact Database File: When the backup and delete or delete only functions are executed, the deleted data is removed from the database but the disk space the data occupied in the database file is not. The compaction function creates a new copy of the database with the excess space removed, creating a smaller, better organized and, therefore, more responsive database. If CDS functions such as opening or refreshing a data viewer grow noticeably less responsive over time, compaction of the database may help. It is recommended that compaction function be executed at least once a year.

Statistics

A "Statistics" tab page allows users to view a summary page that lists:

1. The total results in the database,
2. The date and time of the oldest result in the database,
3. The date and time of the newest result in the database, and
4. A breakdown of the total results in the database by Result Type and Method.



Total Results in Database: 86172

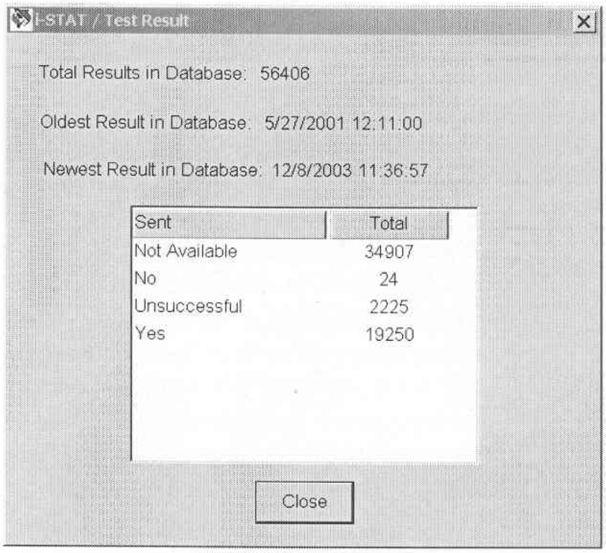
Oldest Result in Database: 5/27/2001 12:11:00

Newest Result in Database: 12/18/2003 10:06:15

Result Type	Method	Total
Test Result	i-STAT	56406
Electronic Simulator	i-STAT	20981
Quality Check Code	i-STAT	3222
Control Result	i-STAT	1024
Cal/Ver Result	i-STAT	604
Proficiency Result	i-STAT	79
Test Result	Precision PCx	914
Quality Check Code	Precision PCx	56
Control Result	Precision PCx	1111

Selecting an individual Result Type and then clicking on Details allows you to view a similar statistical breakdown for that particular Result Type:

1. The total number of that particular Result Type in the database,
2. The date and time of the oldest result of that type in the database,
3. The date and time of the newest result of that type in the database,
4. A breakdown of the number of this particular result type that have been sent successfully (Yes), unsuccessfully, or not sent at all (No) to the LIS/HIS. Note: a listing in this window for "Not Available" indicates that there are records of this type in the database where the details data have been deleted, so the application cannot determine whether that particular record was sent or not.



Total Results in Database: 56406

Oldest Result in Database: 5/27/2001 12:11:00

Newest Result in Database: 12/8/2003 11:36:57

Sent	Total
Not Available	34907
No	24
Unsuccessful	2225
Yes	19250

INVENTORY WORKSPACE

Overview

The Inventory Workspace is organized under five tabs with the following functions:

- Stock: define reorder triggers, view and edit inventory
- Distribution: track items distributed from central stock to different locations
- Orders: track pending and received orders, view reports on received items
- Items: define inventory items
- Inventory log: view a log of major user actions

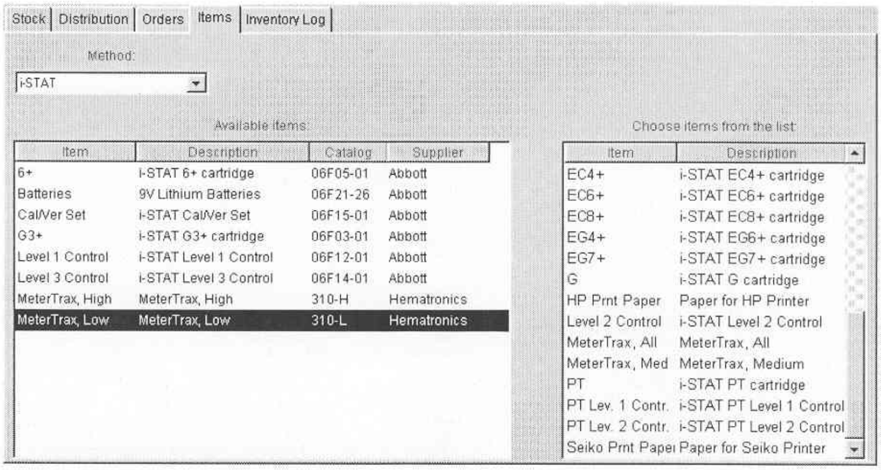
Populate the Items tab first, followed by the Stock tab where current inventory should be entered and reorder triggers defined.

Items

The Items tab is used to define the inventory items for the i-STAT System and other point-of-care tests.

To select an item available from i-STAT and its distributors, highlight the item in the **Choose items from the list** on the right side of the window, then click the arrow next to the **Add** button in the tool bar and click the **Selected** button. The item will move to the **Available items** list on the left side of the window.

To add an item not available from i-STAT and its distributors, click the arrow next to the **Add** button in the tool bar, then click the **New** button and complete the displayed information form.



Method: i-STAT

Available items:

Item	Description	Catalog	Supplier
6+	i-STAT 6+ cartridge	06F05-01	Abbott
Batteries	9V Lithium Batteries	06F21-26	Abbott
Cal/Ver Set	i-STAT Cal/Ver Set	06F15-01	Abbott
G3+	i-STAT G3+ cartridge	06F03-01	Abbott
Level 1 Control	i-STAT Level 1 Control	06F12-01	Abbott
Level 3 Control	i-STAT Level 3 Control	06F14-01	Abbott
MeterTrax, High	MeterTrax, High	310-H	Hematronics
MeterTrax, Low	MeterTrax, Low	310-L	Hematronics

Choose items from the list:

Item	Description
EC4+	i-STAT EC4+ cartridge
EC6+	i-STAT EC6+ cartridge
EC8+	i-STAT EC8+ cartridge
EG4+	i-STAT EG6+ cartridge
EG7+	i-STAT EG7+ cartridge
G	i-STAT G cartridge
HP Prnt Paper	Paper for HP Printer
Level 2 Control	i-STAT Level 2 Control
MeterTrax, All	MeterTrax, All
MeterTrax, Med	MeterTrax, Medium
PT	i-STAT PT cartridge
PT Lev. 1 Contr.	i-STAT PT Level 1 Control
PT Lev. 2 Contr.	i-STAT PT Level 2 Control
Seiko Prnt Papei	Paper for Seiko Printer

To delete an item from the Available items list, highlight the item, then click the **Delete** button in the tool bar. If the item was selected from **Chose items from the list**, the item will be moved from **Available items** back to this list.

To edit information under the **Available items** list, click the **Edit** button in the tool bar.

Stock

The Stock tab includes both Inventory and Estimated Inventory statistics.

Inventory: The number of given items as counted and entered by the user. The inventory is automatically updated when new orders are received under the Orders tab.

Estimated Inventory: The number of i-STAT cartridges and MediSense PCx and/or PCx Plus glucose test strips as estimated by the workspace software. The initial Estimated Inventory is taken from the Inventory column. Every time a cartridge or glucose test strip result is transmitted to the Central Data Station software, the count of the estimated inventory decreases by 1. The Estimated Inventory is automatically updated when new orders are received under the Orders tab. The Estimated Inventory item count is adjusted to the Inventory count whenever the Inventory column is manually edited.

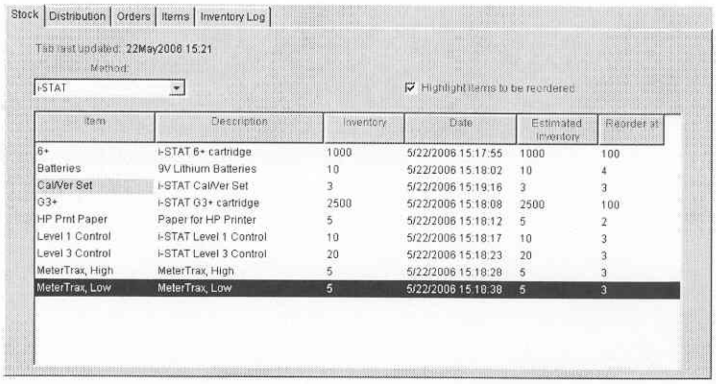
Startup Option

The items added under the Items tab will be listed under the Stock tab with **Inventory** and **Reorder** set to 0. There are two ways to populate the Inventory column.

1. Count current stock. Go to the Stock tab, click on the **Edit** button in the tool bar, and enter the current inventory. Lot numbers and Expiration dates will not be tracked for inventory entered by this method.
2. Count current stock along with lot numbers, expiration dates and locations. Go to the Order tab and enter and receive the POs for the existing stock. Go to the Stock tab and manually adjust the Inventory to the current stock count. (Alternatively, receive only the current stock count.) This option allows the user to take advantage of the lot number and expiration date tracking capabilities of the workspace.

Click on the Edit button on the tool bar and enter the reorder trigger numbers.

Click a check mark next to **Highlight items to be reordered**. Items that need to be reordered will be highlighted. (See CalVer Set in illustration below.) Reorders are highlighted based on the **Estimated Inventory**.



Tab last updated: 22May2006 15:21

Method: i-STAT

☑ Highlight items to be reordered

Item	Description	Inventory	Date	Estimated Inventory	Reorder at
6+	i-STAT 6+ cartridge	1000	5/22/2006 15:17:55	1000	100
Batteries	9V Lithium Batteries	10	5/22/2006 15:18:02	10	4
CalVer Set	i-STAT CalVer Set	3	5/22/2006 15:19:16	3	3
G3+	i-STAT G3+ cartridge	2500	5/22/2006 15:18:08	2500	100
HP Prnt Paper	Paper for HP Printer	5	5/22/2006 15:18:12	5	2
Level 1 Control	i-STAT Level 1 Control	10	5/22/2006 15:18:17	10	3
Level 3 Control	i-STAT Level 3 Control	20	5/22/2006 15:18:23	20	3
MeterTrax, High	MeterTrax, High	5	5/22/2006 15:18:28	5	3
MeterTrax, Low	MeterTrax, Low	5	5/22/2006 15:18:38	5	3

The inventory can be edited by highlighting the item and clicking the **Edit** button or by clicking the **Adjust Invent** button, selecting the item from the drop down menu, and adding or subtracting units. When the **Inventory** is edited, the **Estimated Inventory** is automatically made equal to the **Inventory**.

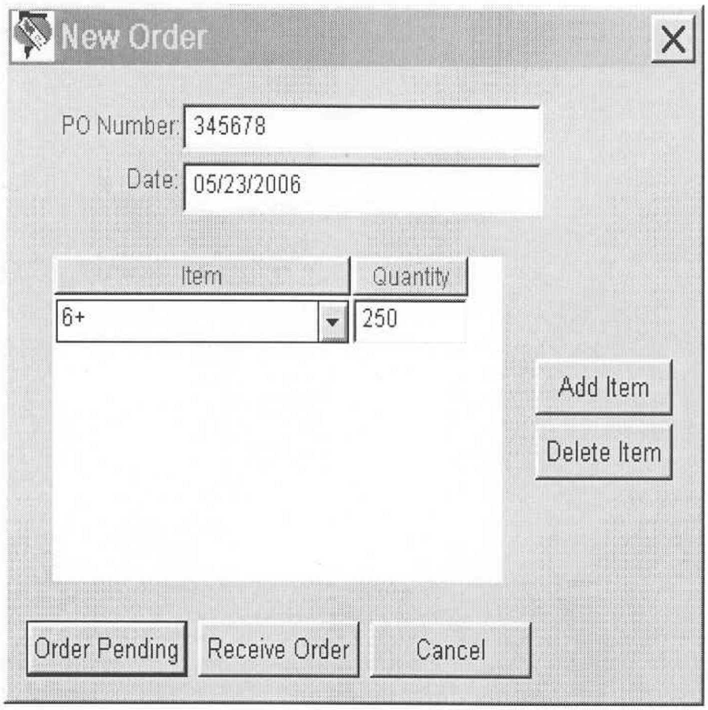
The **Estimated Inventory** for i-STAT cartridges and MediSense PCx glucose test strips will automatically begin updating with the next analyzer transmission. Click the **Refresh** button to update the workspace for transmitted data. Both the **Inventory** and the **Estimated Inventory** are updated automatically when orders are received under the Orders tab.

Periodically, the **Estimated Inventory** should be updated manually. This is necessary to account for other consumables as well as for cartridges and strips that are discarded before testing, such as expired inventory. Click the **Estim. Invent.** button in the tool bar to adjust the **Estimated Inventory**.

Orders

To record a new order, click on the **Add** button in the tool bar. Select the item from the drop down menu under **Item** and enter the quantity. Click the **Add Item** button to add another item or the **Delete Item** button to delete an item.

To enter information about a received order right away, click on the **Receive Order** button. To enter information about a received order later, click the **Order Pending** button.

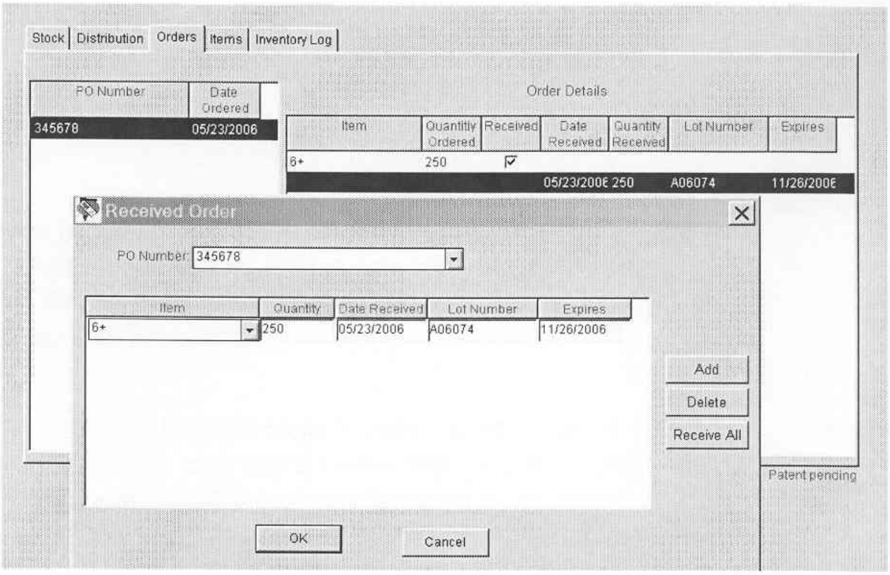


PO Number: 345678
Date: 05/23/2006

Item	Quantity
6+	250

To receive an item or to edit order information, click the **Edit/Receive** button in the tool bar. Highlight the PO Number and enter the **Order Details**.

Note: The lot number and expiration date are used in the Distribution tab. Therefore, PO, lot number and expiration date information for consumables in inventory should be entered here. The PO number field can accommodate up to 20 characters.


Stock
Distribution
Orders
Items
Inventory Log
Order Details
Received Order
Add
Delete
Receive All
OK
Cancel
Patent pending

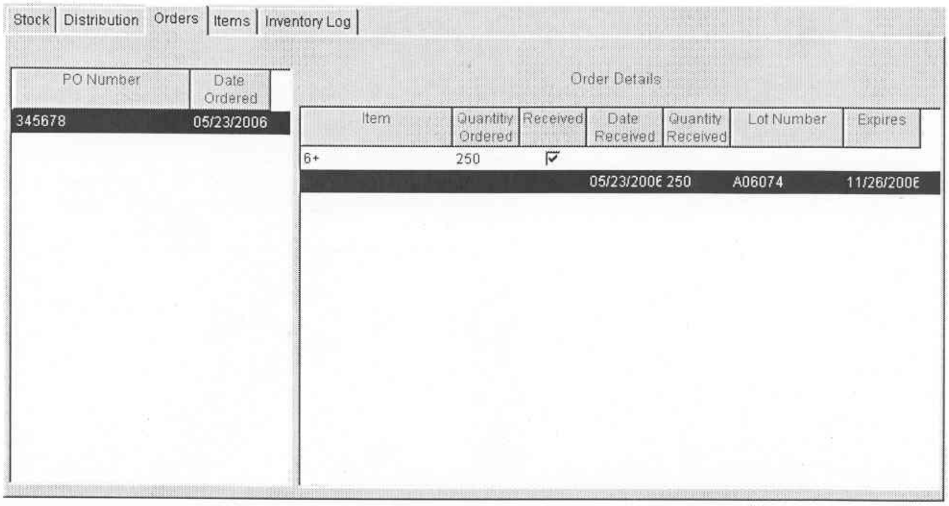
PO Number	Date Ordered
345678	05/23/2006

Item	Quantity Ordered	Received	Date Received	Quantity Received	Lot Number	Expires
6+	250	☑				
			05/23/2006	250	A06074	11/26/2006

PO Number: 345678

Item	Quantity	Date Received	Lot Number	Expires
6+	250	05/23/2006	A06074	11/26/2006

Click the **Add** Button to add another item or the **Delete** Button to delete an item. Click the **Receive All** Button to automatically enter items and quantities, as they were ordered.


Stock
Distribution
Orders
Items
Inventory Log
Order Details

PO Number	Date Ordered
345678	05/23/2006

Item	Quantity Ordered	Received	Date Received	Quantity Received	Lot Number	Expires
6+	250	☑				
			05/23/2006	250	A06074	11/26/2006

Use the **Delete** button on the tool bar to delete an order.

Use the **Find Lot** and **Find Next** buttons on the tool bar to find the PO associated with a received lot.

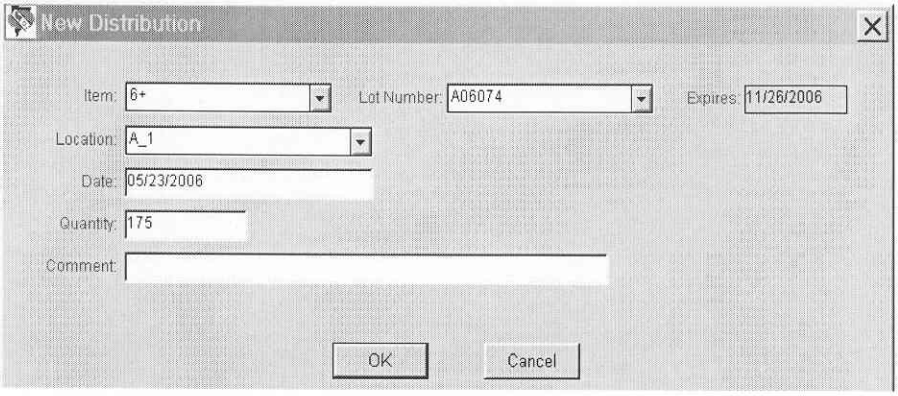
Use the **Delete Lot** button on the tool bar to delete a lot number that has expired or has been used up.

The **Report** button on the tool bar is used to view all received items by date range.

Use the **Add Note** button on the tool bar to add a note to the **Inventory Log**.

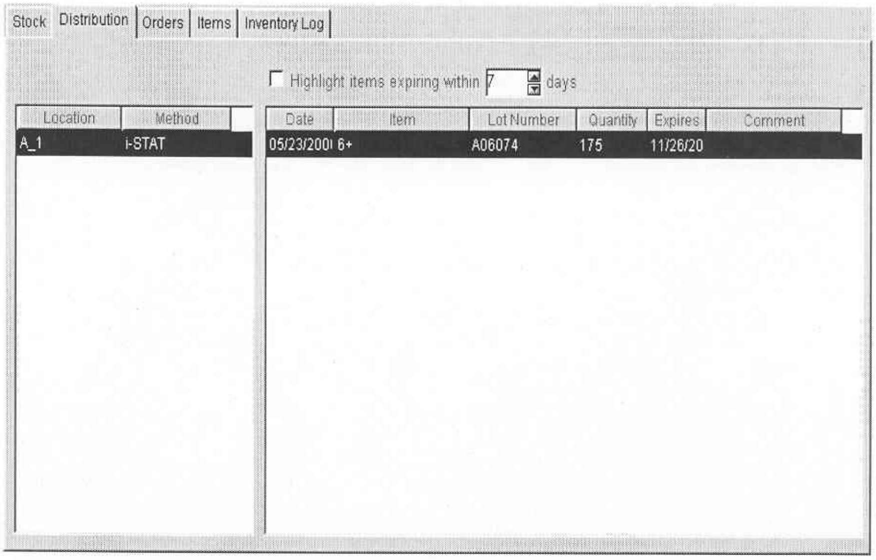
Distribution

Use the **Add** button in the tool bar to record the distribution of consumables. The Item drop down menu includes all consumables entered in the Items tab. The Location drop down menu includes all locations entered in the Instrument and Location Workspace. The Lot Number drop down menu includes lot numbers for the selected items received in the Order tab. The expiration date is entered automatically. A comment of up to 16 characters can be entered.



Item: 6+
Lot Number: A06074
Expires: 11/26/2006
Location: A_1
Date: 05/23/2006
Quantity: 175
Comment:

The Distribution tab will list each location with its consumables. Define an alert date and click a check mark next to **Highlight items expiring within xx days** to alert you to transfer stock to a different location where it can be used before its expiration date.



☐ Highlight items expiring within 7 days

Location	Method
A_1	i-STAT

Date	Item	Lot Number	Quantity	Expires	Comment
05/23/200	6+	A06074	175	11/26/20	

Use the **Delete** button on the tool bar to delete a distribution.

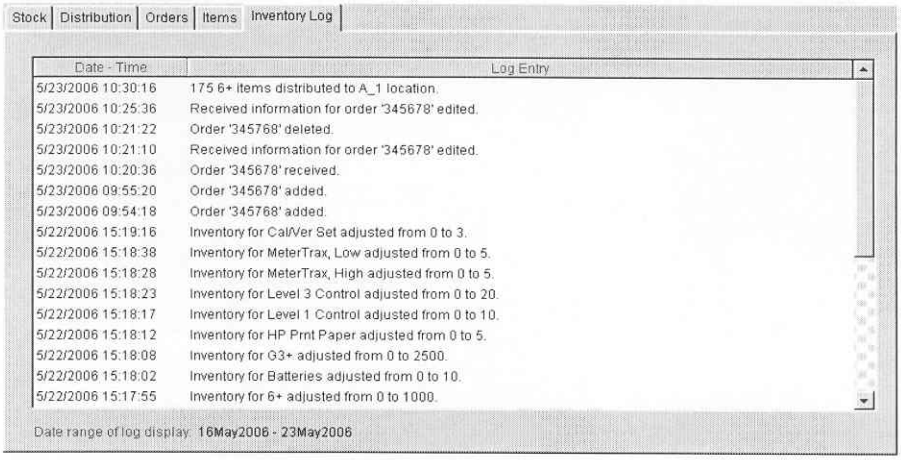
Use the **Transfer** button in the toolbar to move consumables from one location to another.

Use the **Find Lot** button to find a location where a consumable of a specific lot has been distributed. Click the **Find Next** button to find other locations for this lot.

Use the **Add Note** button to add a note to the Inventory Log.

Inventory Log

The Inventory Log documents each action taken in the Items, Stock, Distribution and Orders tabs. Click the **Date Range** button in the toolbar to select the a Default date range or a Start and End date for this report. Click the Delete button to delete entries in the log.



Date - Time	Log Entry
5/23/2006 10:30:16	175 6+ items distributed to A_1 location.
5/23/2006 10:25:36	Received information for order '345678' edited.
5/23/2006 10:21:22	Order '345768' deleted.
5/23/2006 10:21:10	Received information for order '345678' edited.
5/23/2006 10:20:36	Order '345678' received.
5/23/2006 09:55:20	Order '345678' added.
5/23/2006 09:54:18	Order '345768' added.
5/22/2006 15:19:16	Inventory for Cal/Ver Set adjusted from 0 to 3.
5/22/2006 15:18:38	Inventory for MeterTrax, Low adjusted from 0 to 5.
5/22/2006 15:18:28	Inventory for MeterTrax, High adjusted from 0 to 5.
5/22/2006 15:18:23	Inventory for Level 3 Control adjusted from 0 to 20.
5/22/2006 15:18:17	Inventory for Level 1 Control adjusted from 0 to 10.
5/22/2006 15:18:12	Inventory for HP Prnt Paper adjusted from 0 to 5.
5/22/2006 15:18:08	Inventory for G3+ adjusted from 0 to 2500.
5/22/2006 15:18:02	Inventory for Batteries adjusted from 0 to 10.
5/22/2006 15:17:55	Inventory for 6+ adjusted from 0 to 1000.

Date range of log display: 16May2006 - 23May2006

CUSTOMIZATION WORKSPACE

Overview

This workspace is used to create profiles with site specific test characteristics for the analyzers. See the Customization section of this manual for details of items that can be customized and their default settings.

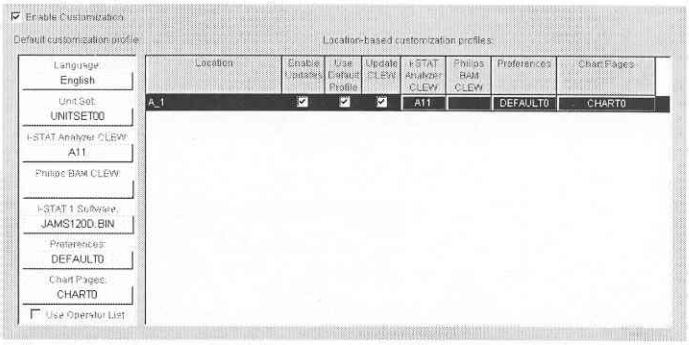
Password

The Customization Workspace is password protected. If the Security feature is disabled, the default password is **istat**. If the Security feature is enabled, the user uses the same password as their CDS application logon password. To change the password, select **Tools** and **Change Password** from the menu bar. A password from 3 to 8 characters can be used.

Enabling Customization

To enable customization, click the box to check it. When customization is enabled, the Central Data Station will check the Customization Profile for the location each time an analyzer is downloaded. If the location has the **Enable Updates** option checked, the Central Data Station will update the analyzer with the current Customization Profile for that location as noted below.

- Analyzers designated to Report location as download location in the Instrument workspace will be updated with the Customization Profile assigned to the download location, regardless of the location to which the instrument is assigned. Care should be taken when downloading instruments from locations other then their assigned location.
- Analyzers designated to Always report location as this assignment in the Instrument workspace will always be updated with the Customization Profile for the instrument's assigned location, regardless of the physical location from which it downloads.



☑ Enable Customization

Default customization profile:

Language: English

Unit Set: UNITSET00

i-STAT Analyzer CLEW: A11

Philips BAM CLEW:

i-STAT 1 Software: JAMS120D.BIN

Preferences: DEFAULT0

Chart Pages: CHART0

☐ Use Operator List

Location-based customization profiles:

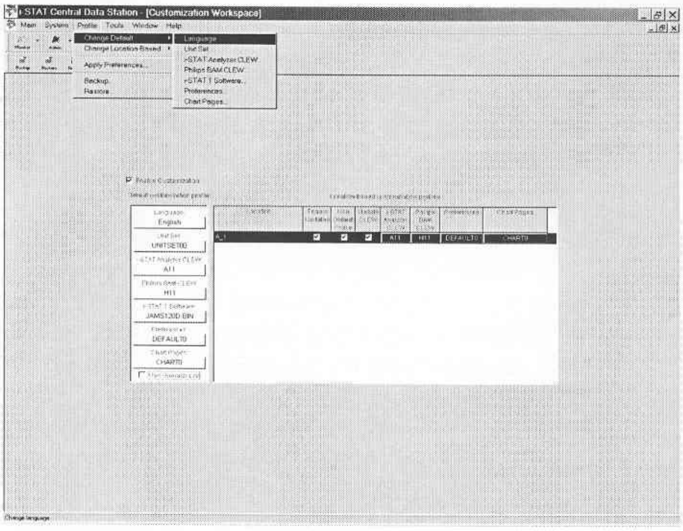
Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	Chart Pages
A_1	☑	☑	☑	A11		DEFAULT0	CHART0

If a location has the **Enable Updates** option unchecked, downloading from that location will result in no customization changes being made to analyzers designated to **Report location as download location.** Analyzers designated to **Always report location as this assignment** will not be updated if the assignment location for the instrument has the **Enable Updates** option unchecked, regardless of the setting associated with the physical location from which it downloads.

User can also disable/enable CLEW updates by location. The default setting is to have the CLEW updates occur automatically for all locations. To disable a particular location, simply click on the corresponding check box under **Update CLEW** to remove the check mark.

Default Customization Profile

The first step in customization is to create a default customization profile. This is the profile initially assigned to every new location. To change the default profile, use the directions under Making Selections or click the menu option **Profile ➪ Change Default** and the item to be changed. The changes in the default profile are automatically applied to every location using the default profile.

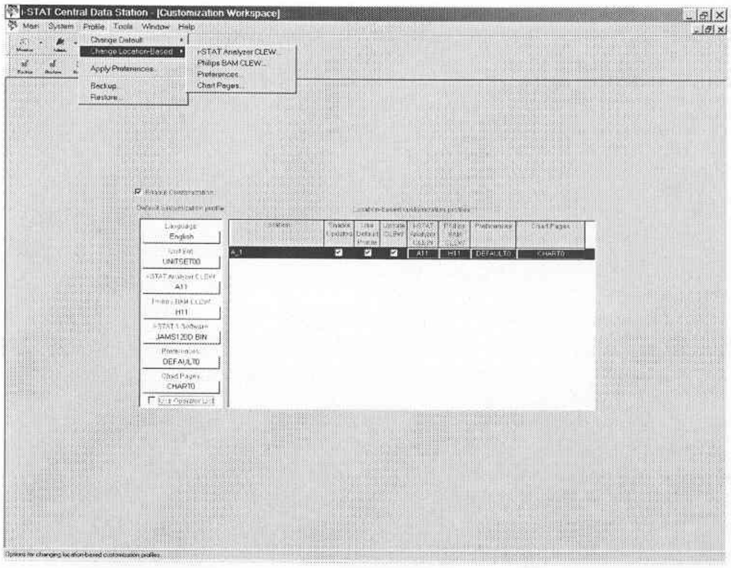

i-STAT Central Data Station - [Customization Workspace]
Main System Profile Tools Window Help
Change Default
Change Location-Based
Apply Preferences...
Backup...
Restore...
Language
Unit Set
i-STAT Analyzer CLEW...
Philips BAM CLEW...
i-STAT 1 Software...
Preferences...
Chart Pages...
Change language.

Language: English
Unit Set: UNITSET00
i-STAT Analyzer CLEW: A11
Philips BAM CLEW: H11
i-STAT 1 Software: JAMS120D.BIN
Preferences: DEFAULT0
Chart Pages: CHART0

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	Chart Pages
A_1	☑	☑	☑	A11	H11	DEFAULT0	CHART0

Location-based Customization Profiles

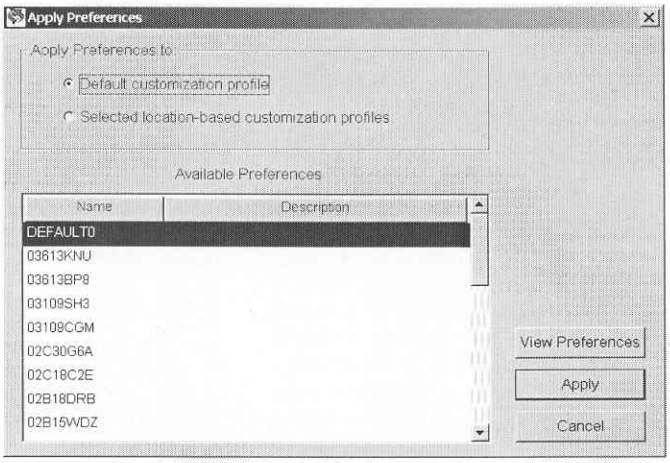
Different customization profiles can be created for different locations. Uncheck the **Use Default Profile** box for the location and double click **i-STAT Analyzer CLEW** or **BAM CLEW** to change the CLEW or double click **Preferences** to change any of the preferences. Alternately, select the menu option **Profile ➪ Change Location-Based** and the item to be changed. Changes in the customization profile can be made for several locations at once by selecting the locations and then selecting the appropriate option from the Profile Menu. If a location has the **Use Default Profile** option checked, its customization settings will not be changed even if it is selected. Note that Language and the Unit Set from the default customization profile are always used.


i-STAT Central Data Station - [Customization Workspace]
Main System Profile Tools Window Help
Change Default
Change Location-Based
Apply Preferences...
Backup...
Restore...
i-STAT Analyzer CLEW...
Philips BAM CLEW...
Preferences...
Chart Pages...
Options for changing location-based customization profiles.

Language: English
Unit Set: UNITSET00
i-STAT Analyzer CLEW: A11
Philips BAM CLEW: H11
i-STAT 1 Software: JAMS120D.BIN
Preferences: DEFAULT0
Chart Pages: CHART0

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences	Chart Pages
A_1	☑	☑	☑	A11	H11	DEFAULT0	CHART0

Preferences for locations can also be changed by selecting an existing preference from the Apply Preferences submenu. Select the location or locations to be changed. Click **Profile** ➪ **Apply Preferences.** Select the desired preferences and click **Apply**. Click **View Preferences** to review a set of preferences.


Apply Preferences
Apply Preferences to
Available Preferences
View Preferences
Apply
Cancel

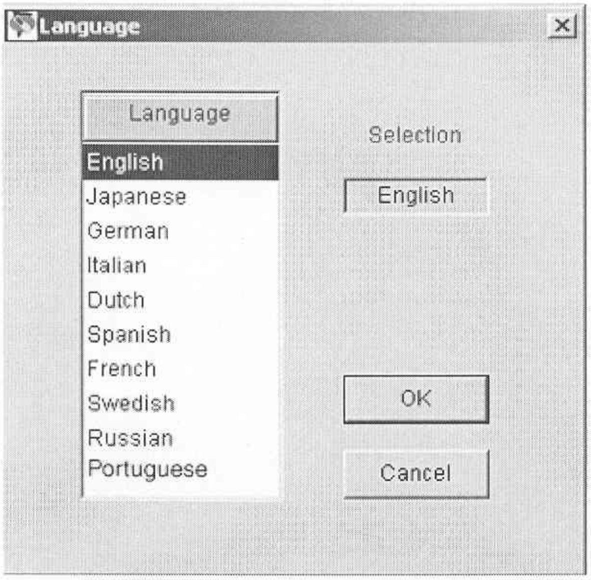
● Default customization profile
○ Selected location-based customization profiles

Name	Description
DEFAULT0	
03613KNU	
03613BP8	
03109SH3	
03109CGM	
02C30G6A	
02C18C2E	
02B18DRB	
02B15WDZ	

Making Selections Selections are made from options in the following ways:

- Select one of the seven main Customization options by double clicking the box for **Language**, **Unit Set**, **i-STAT Analyzer CLEW, Philips BAM CLEW, i-STAT 1 Software, Preferences, or Chart Pages**.
- After making a selection in the Language, Unit Set and CLEW window, click the **OK** button to save the selection or click the **Cancel** button to return to the previous selection.

Language Window

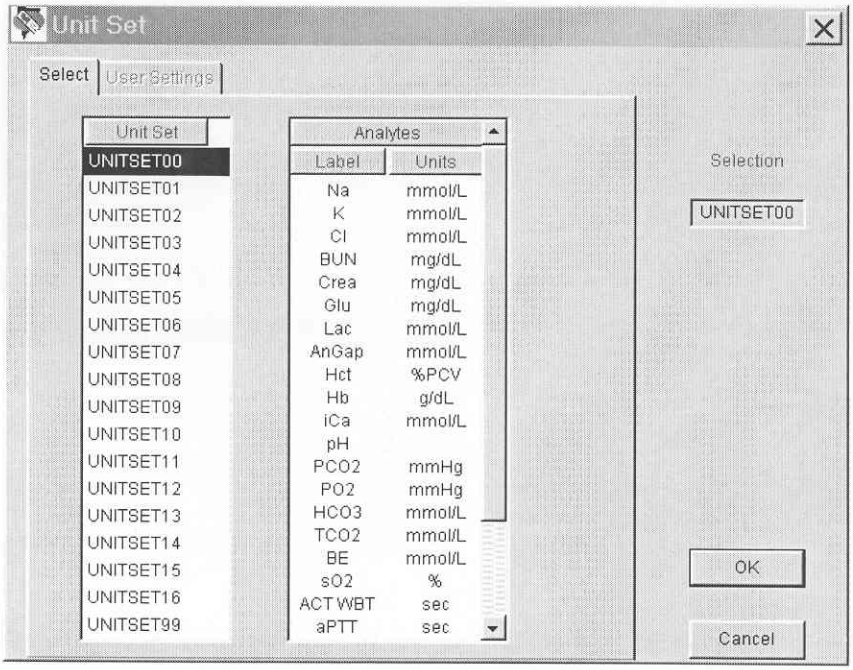

Language
Language
English
Japanese
German
Italian
Dutch
Spanish
French
Swedish
Russian
Portuguese
OK
Cancel

Selection: English

Note: Russian is available only on the i-STAT Portable Clinical Analyzer and Portuguese, Danish, and Finnish are available only on the i-STAT 1 Analyzer.

Unit Set Window

Details of each unit set are displayed under the Analytes column. Details are also listed in the Customization section in this manual.



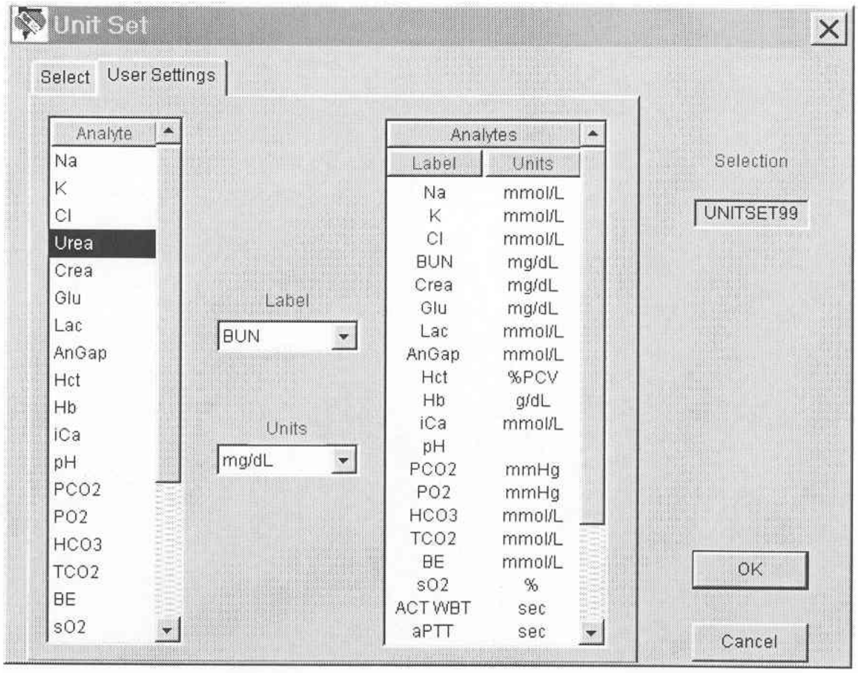
Unit Set
UNITSET00
UNITSET01
UNITSET02
UNITSET03
UNITSET04
UNITSET05
UNITSET06
UNITSET07
UNITSET08
UNITSET09
UNITSET10
UNITSET11
UNITSET12
UNITSET13
UNITSET14
UNITSET15
UNITSET16
UNITSET99

Analytes

Label	Units
Na	mmol/L
K	mmol/L
Cl	mmol/L
BUN	mg/dL
Crea	mg/dL
Glu	mg/dL
Lac	mmol/L
AnGap	mmol/L
Hct	%PCV
Hb	g/dL
iCa	mmol/L
pH	
PCO2	mmHg
PO2	mmHg
HCO3	mmol/L
TCO2	mmol/L
BE	mmol/L
sO2	%
ACT WBT	sec
aPTT	sec

Selection: UNITSET00

To create a unique unit set, click **UNITSET99** and then the **User Settings** tab. Then select the name and units for each analyte or test.



Analyte
Na
K
Cl
Urea
Crea
Glu
Lac
AnGap
Hct
Hb
iCa
pH
PCO2
PO2
HCO3
TCO2
BE
sO2

Label: BUN

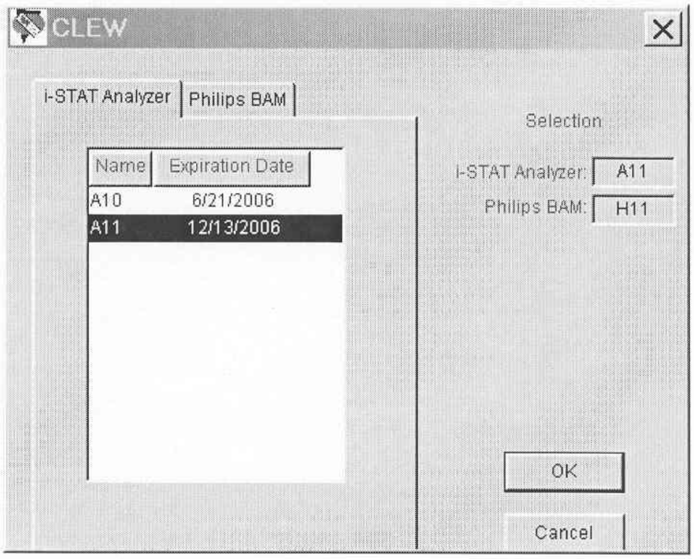
Units: mg/dL

Analytes

Label	Units
Na	mmol/L
K	mmol/L
Cl	mmol/L
BUN	mg/dL
Crea	mg/dL
Glu	mg/dL
Lac	mmol/L
AnGap	mmol/L
Hct	%PCV
Hb	g/dL
iCa	mmol/L
pH	
PCO2	mmHg
PO2	mmHg
HCO3	mmol/L
TCO2	mmol/L
BE	mmol/L
sO2	%
ACT WBT	sec
aPTT	sec

Selection: UNITSET99

i-STAT Analyzer and Philips BAM CLEW Windows



Name	Expiration Date
A10	6/21/2006
A11	12/13/2006

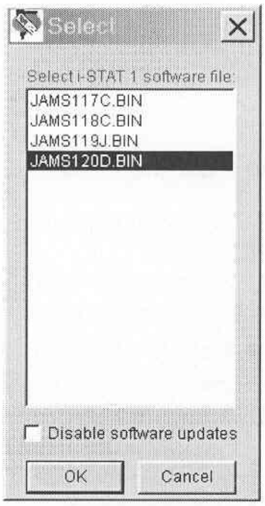
i-STAT Analyzer: A11
Philips BAM: H11

A new CLEW is added to the window via the software update process twice a year. If the **Update CLEWs** feature is active, the Default customization profile must be updated after each new CLEW is added. Click the new CLEW and click OK. Note that there are separate CLEWs for the i-STAT analyzer and the Philips Blood Analysis Module.

Note: Before changing to a new CLEW ensure that all analyzers have been updated to a compatible application software version.

i-STAT 1 Software Window

A new JAMS application software is added to the window via the software update process twice a year. Click the new JAMS and click OK. Selecting the new JAMS aloows users the option of updating their i-STAT 1 analyzers remotely or locally using the Customization Workspace. Please see the Technical Bulletin "Updating Analyzer Software" for full details on performing this procedure. Checking "Disable Software Updates" disables this feature.

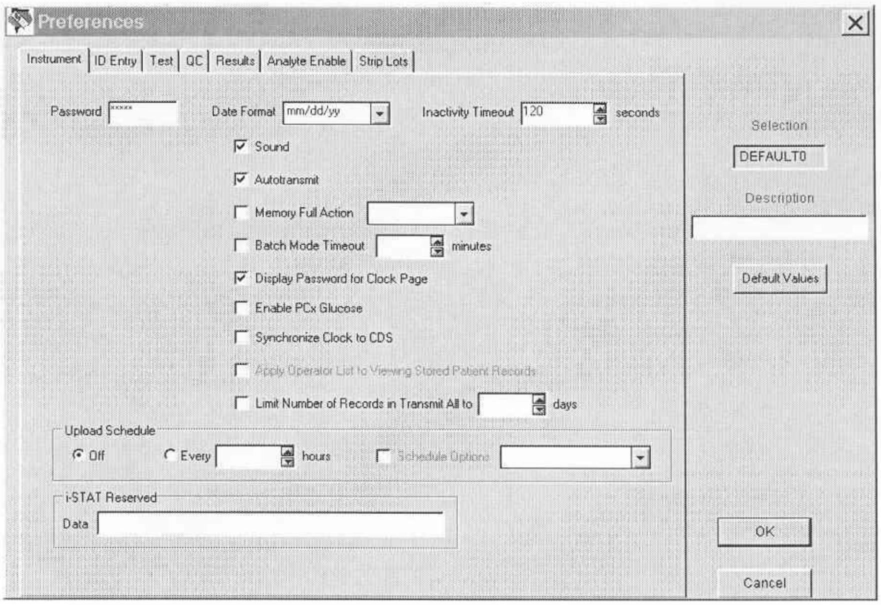


Select i-STAT 1 software file:

JAMS117C.BIN
JAMS118C.BIN
JAMS119J.BIN
JAMS120D.BIN

☐ Disable software updates

Preferences Window


Preferences
Instrument | ID Entry | Test | QC | Results | Analyte Enable | Strip Lots
Default Values
OK
Cancel

Password *****
Date Format mm/dd/yy
Inactivity Timeout 120 seconds
☑ Sound
☑ Autotransmit
☐ Memory Full Action
☐ Batch Mode Timeout minutes
☑ Display Password for Clock Page
☐ Enable PCx Glucose
☐ Synchronize Clock to CDS
☐ Apply Operator List to Viewing Stored Patient Records
☐ Limit Number of Records in Transmit All to days

Upload Schedule
● Off ○ Every hours ☐ Schedule Options

i-STAT Reserved
Data

Selection
DEFAULT0
Description

For detailed descriptions of the preferences, see section 9, Customization. The Preferences Window has seven tab pages. Click the tab to display the desired page. The following conventions are used in the Preferences pages:

- Enable/disable an option by clicking the check box to check/uncheck it.
- Change a numeric setting by clicking and holding the ▲ or ▼ symbol or manually entering the number.
- Select an option from a list by clicking the ▼, and selecting the option from the list.
- Select from multiple options by clicking the radio button next to the desired option.
- Enter values into fields, such as for Reference Ranges and Strip Lot Numbers.

When all information has been entered, a button is pressed:

- **Default Values** will restore the default settings to the open window.
- **OK** will store the new settings.
- **Cancel** will ignore any new settings and restore the current settings.

Each Customization Profile is assigned a unique name by the CDS program. This name appears under the Preferences column in the Customization Workspace window, on the Customization screen on the i-STAT 1 Analyzer, on the Analyzer Status screen on the i-STAT Portable Clinical Analyzer and on the Blood Analysis Setup screen of the Blood Analysis Module.

A description can be associated with a profile using the **Description** field in the Preferences Window.

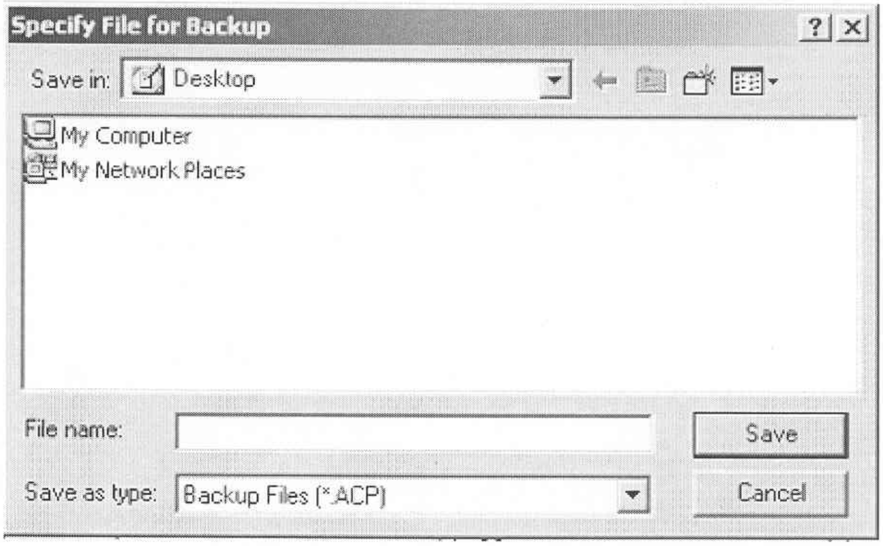
Caution: Close the Customization Workspace when finished to prevent inadvertent changes.

Chart Page Selection Box

The Chart Page selection box is part of a feature allowing users to customize the Chart Page on their i-STAT 1 analyzers in order to capture user-defined information such as ventillator settings. See the "i-STAT 1 Analyzer Chart Page Customization" Technical Bulletin for full details.

Backup and Restore Profile

The current customization profile can be stored by selecting **Profile ⇨ Backup...** from the menu bar or by clicking the **Backup** toolbar button, selecting the directory where the profile is to be stored, typing in a file name for the profile, and clicking the **Save** button.

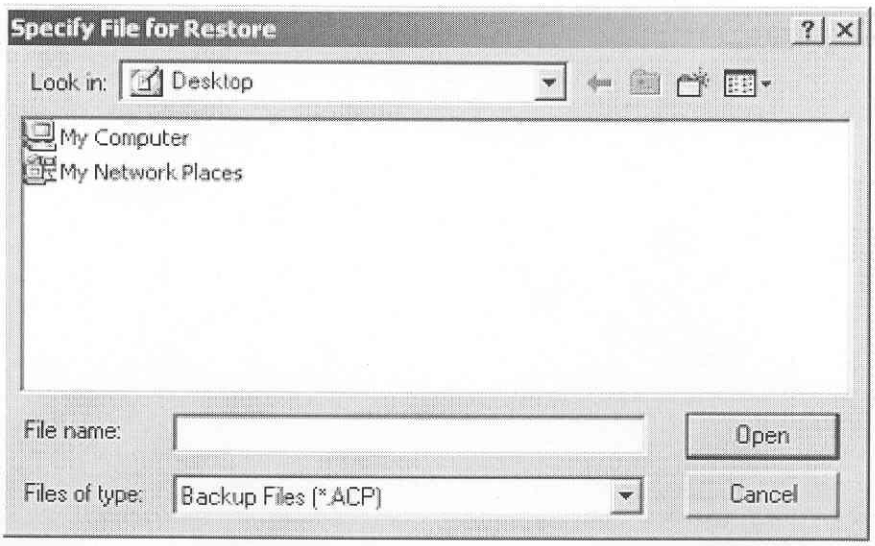


Save in: Desktop

Save as type: Backup Files (*.ACP)

Specify File for Backup
?
My Computer
My Network Places
File name:
Save
Cancel

To restore a profile to the CDS, click **Profile ⇨ Restore...** or the **Restore** toolbar button. Select the directory and backup file to restore and click the **Open** button.



Look in: Desktop

Files of type: Backup Files (*.ACP)

Specify File for Restore
?
My Computer
My Network Places
File name:
Open
Cancel

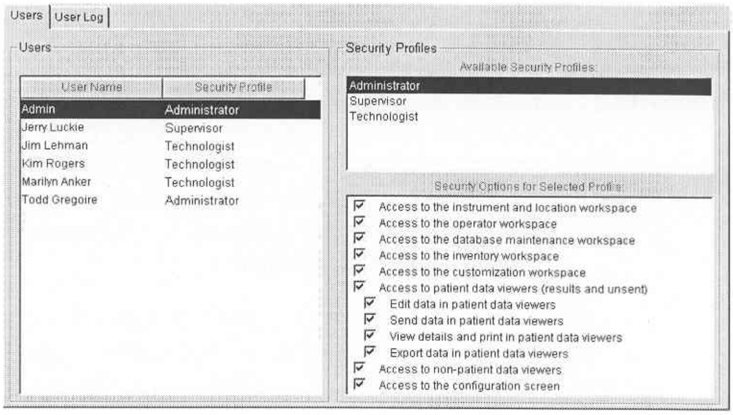
USER ADMINISTRATION WORKSPACE

Overview

The User Administration Workspace is designed as a tool for system administrators. It allows administrators to manage security profiles (a set of security settings determining the access to different CDS screens and functions), manage users, and assign users to security profiles.

Access

Only users designated as administrators can access the User Administration Workspace in the CDS by clicking on **Main ➪ Open Administration Function ➪ User Administration**. A Password dialog will then appear. Type in your CDS log-in password and click on **OK**.


Users
User Log
Users
Security Profiles
Available Security Profiles:
Security Options for Selected Profile:

User Name	Security Profile
Admin	Administrator
Jerry Luckie	Supervisor
Jim Lehman	Technologist
Kim Rogers	Technologist
Marilyn Anker	Technologist
Todd Gregoire	Administrator

Administrator
Supervisor
Technologist

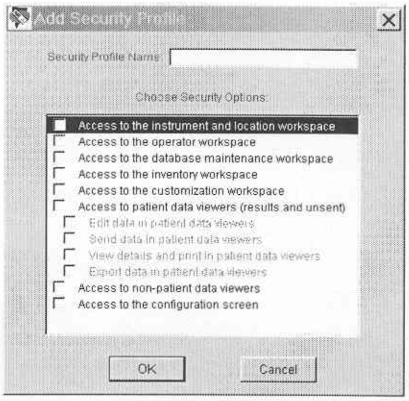
- ☑ Access to the instrument and location workspace
- ☑ Access to the operator workspace
- ☑ Access to the database maintenance workspace
- ☑ Access to the inventory workspace
- ☑ Access to the customization workspace
- ☑ Access to patient data viewers (results and unsent)
  - ☑ Edit data in patient data viewers
  - ☑ Send data in patient data viewers
  - ☑ View details and print in patient data viewers
  - ☑ Export data in patient data viewers
- ☑ Access to non-patient data viewers
- ☑ Access to the configuration screen

Creating Security Profiles

Once the User Administration Workspace is activated, the Administrator will need to determine how many different security profiles are needed for their facility, and what workspaces and functions should be available to users at those different security levels. Once those decisions have been made, the next step is to create the desired security profiles in the User Administration Workspace.

Please note that an Administrator profile will always exist in the User Administration Workspace. It cannot be edited or deleted, and allows access for those designated users to all CDS Workspaces and functions.

To create a new security profile: click on **Profile ➪ Add...** An "Add Security Profile" dialog will then appear.



Security Profile Name:

- ☐ Access to the instrument and location workspace
- ☐ Access to the operator workspace
- ☐ Access to the database maintenance workspace
- ☐ Access to the inventory workspace
- ☐ Access to the customization workspace
- ☐ Access to patient data viewers (results and unsent)
  - ☐ Edit data in patient data viewers
  - ☐ Send data in patient data viewers
  - ☐ View details and print in patient data viewers
  - ☐ Export data in patient data viewers
- ☐ Access to non-patient data viewers
- ☐ Access to the configuration screen

Type in the name of the new Security Profile, then check off the different workspaces and functions users assigned to that security level will be allowed to access, and then click **OK**. The newly created security profile will then be added to the Available Security Profile list.

Deleting Security Profiles

To delete an existing Security Profile, click on the profile you want to delete in the Available Security Profiles window. Click on **Profile ➪ Delete**, and answer **"Yes"** to the confirmation message that appears on the screen.

Please note that a Security Profile can only be deleted if all of the Users assigned to that particular profile have first been deleted from the Users window. If all of the users have not first been deleted, "Error Accessing Database" and "Error Deleting Profile" messages will appear.

The Administrator Security Profile is permanent and cannot be deleted.

Editing Security Profiles

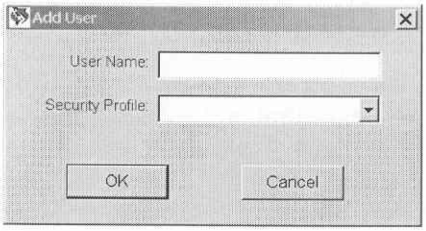
To edit an existing Security Profile, click on the profile you want to edit in the Available Security Profiles window. Click on **Profile ➪ Edit**. The name of the profile will then be highlighted in blue. If you wish to edit the profile name, simply type in the new profile name. Then select or deselect the desired listings under the "Security Options for Selected Profile" window by clicking on the corresponding check box.

When all edits are complete, simply click on **Profile ➪ Edit**, and answer **Yes** to the confirmation message that appears about saving the new changes.

Adding Users

Once all the Security Profiles have been created, the next step is to create users and assign them to the various security profile levels.

To add a user to a security profile when in the User Administration Workspace, click on **User ➪ Add....** An Add User box will then appear on the screen.



Type in the User Name in the first line, then choose the appropriate Security Profile from the drop down list and click **OK**. The new user listing will then appear in the User window.

Deleting a User

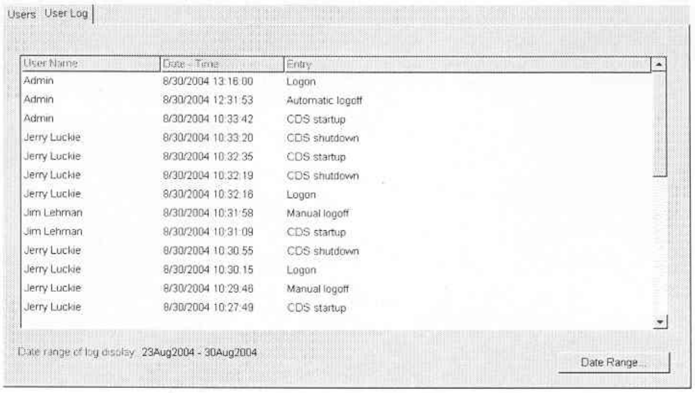
To delete a user, select the user to be deleted, click on **User ➪ Delete**, and answer **Yes** to the confirmation message. Note: the user who is currently logged on cannot be deleted.

Assigning a User to a Different Profile

To assign an existing user to a different Security Profile, click on **User ➪ Assign Profile**. A drop down menu will appear next to the user's name. Simply click on the desired Security Profile, then click on **User ➪ Assign Profile**, and answer **Yes** to the confirmation message that appears asking if you want to save changes.

User Log

The User Log tracks the following user activities: CDS Startup and Shutdown, User Logon, Manual and Automatic User Logoff, and Disabling of the Security feature via the Customization Screen.



User Name	Date - Time	Entry
Admin	8/30/2004 13:16:00	Logon
Admin	8/30/2004 12:31:53	Automatic logoff
Admin	8/30/2004 10:33:42	CDS startup
Jerry Luckie	8/30/2004 10:33:20	CDS shutdown
Jerry Luckie	8/30/2004 10:32:35	CDS startup
Jerry Luckie	8/30/2004 10:32:19	CDS shutdown
Jerry Luckie	8/30/2004 10:32:18	Logon
Jim Lehman	8/30/2004 10:31:58	Manual logoff
Jim Lehman	8/30/2004 10:31:09	CDS startup
Jerry Luckie	8/30/2004 10:30:55	CDS shutdown
Jerry Luckie	8/30/2004 10:30:15	Logon
Jerry Luckie	8/30/2004 10:29:46	Manual logoff
Jerry Luckie	8/30/2004 10:27:49	CDS startup

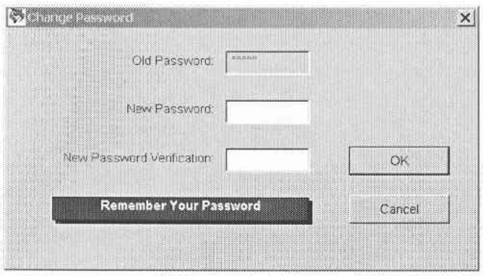
Date range of log display: 23Aug2004 - 30Aug2004

PASSWORD MANAGEMENT

Passwords

Once all the Security Profiles are created, and all CDS users are assigned to the appropriate Profiles, the Administrator should provide the users with their assigned User Names. Their initial password is **istat**.

When a user logs on to the CDS application for the first time, a dialog box asking for a User Name and Password will appear. They should input their assigned User Name supplied by the Administrator, and the password **istat**. A dialog will then appear indicating that they must change their password. After clicking on **OK**, the following dialog will appear:



Old Password: *****

The user should type in a unique password of their choosing in the space provided, then retype that same password on the New Password Verification line and click **OK**. The password must have a minimum length of 3 alphanumeric characters, and a maximum length of 12 alphanumeric characters.

Once the password is changed, the user will then use their new password for all subsequent CDS log-ons.

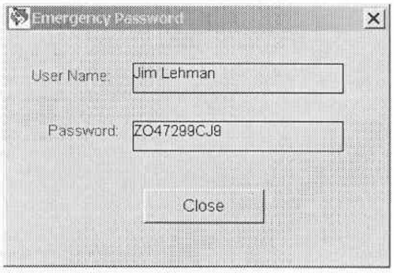
Emergency Passwords

If a user forgets their User Name or Password, they have two options for accessing the CDS application:

1. If available, the Administrator can log onto the User Administration Workspace and look up the User Name from the User Window. An Emergency Password for this particular user can then be obtained by performing the following:

a. Click and highlight this particular user's listing in the User Window.

b. Click on **User ⇨ Emergency Password**. A box will appear with an Emergency Password that this particular user can use. Note: Once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.



User Name: Jim Lehman

Password: ZO47299CJ9

2. If the Administrator is not available, the user can contact their local Support Representative for an emergency User Name and/or password. As with option 1 above, once this user uses the Emergency Password to log in, they will be immediately prompted to change their password for future CDS log-ins. They cannot continue to use the Emergency Password for log-in purposes.

Changing a Password

If a user is logged on to the CDS application, they can choose to change their password at any time by clicking on **Tools ⇨ Change Password**. A dialog box will appear asking them to enter their Old Password, as well as their New Password (twice). After entering this information, the user clicks on **OK** and answers Yes to the question that appears asking if they really want to change password.

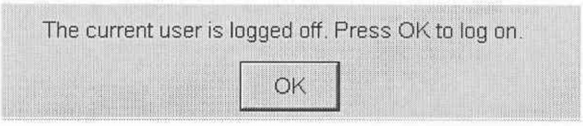
SYSTEM LOGOFFS

Overview

The CDS provides the capability for manual and automatic user logoffs. In the logged off state, the majority of CDS screens and functions are not available. However, analyzer and BAM data can continue to be transmitted to the application, and subsequently sent to the LIS/HIS (if applicable). Also, the monitors remain open if they were open prior to logoff.

Manual Logoff

Once a user has completed their CDS tasks, they can log off by clicking on **System ⇨ Log Off**. A box will then appear on the screen indicating that the current user has logged off.



The current user is logged off. Press OK to log on.

Automatic Logoff

Automatic logoffs are optional and can be enabled in the i-STAT CDS Customization screen, as described in the Security section above on page 22-13.

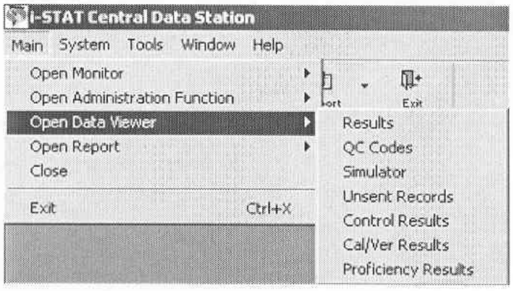
DATA VIEWERS

Overview

Data from instruments downloaded to the CDS are viewed in the Data Viewers.

Data downloaded from the i-STAT 1 Analyzers can be viewed in separate Data Viewers for Results, QC Codes, Simulator, Unsent Results, Control Results, Calibration Verification (or Linearity) Results and Proficiency Results (external quality control).

Control, Calibration Verification and Proficiency Results from the Portable Clinical Analyzers and Blood Analysis Modules will appear in the Results Data Viewer.

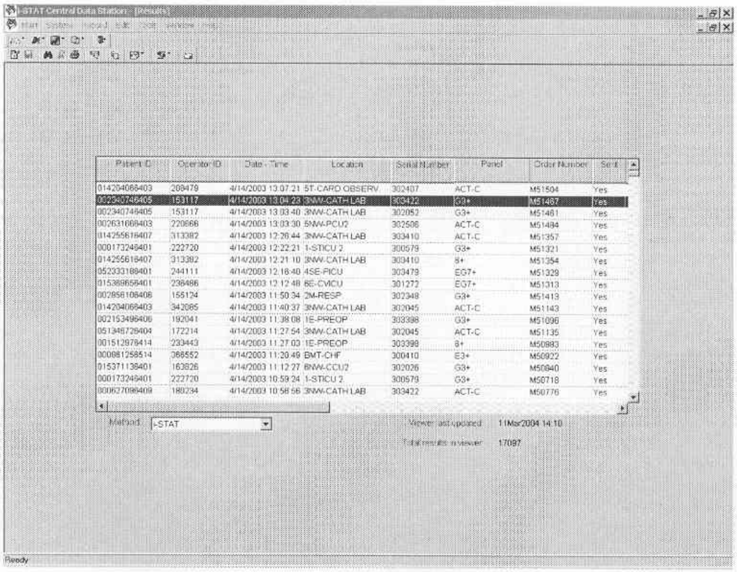


Data from the Medisense Precision PC*x* Plus Glucose Test Strips can now be viewed in the Data Viewers, alongside the data from the Precision PC*x* strip. To determine which strip type was used on a particular testing run, look at the column entitled **Panel**. Precision PC*x* Plus strip runs will be labeled **PCx Plus Glucose**, while Precision PC*x* strip runs will be labeled **PCx Glucose**.

Information in Data Viewers

Data for only one method at a time, such as the i-STAT cartridges, is displayed in a viewer. To switch to a different method, select the method from the selection list in the lower left corner of the viewer. The exception is the Unsent Results Data Viewer which displays results from all methods. Records are listed based on which column is being sorted. Data can be displayed in ascending or descending order by clicking a column as described above.

Example: Results Data Viewer



Patient ID	Operator ID	Date - Time	Location	Serial Number	Panel	Order Number	Sent
014204068403	208479	4/14/2003 13:07:21	5T-CARD OBSERV	302407	ACT-C	M51504	Yes
002340746405	153117	4/14/2003 13:04:23	3NW-CATH LAB	303422	G3+	M51467	Yes
002340746405	153117	4/14/2003 13:03:40	3NW-CATH LAB	302052	G3+	M51461	Yes
002631668403	220666	4/14/2003 13:03:30	5NW-PCU2	302506	ACT-C	M51484	Yes
014255616407	313382	4/14/2003 12:26:44	3NW-CATH LAB	303410	ACT-C	M51357	Yes
000173246401	222720	4/14/2003 12:22:21	1-STICU 2	300579	G3+	M51321	Yes
014255616407	313382	4/14/2003 12:21:10	3NW-CATH LAB	303410	8+	M51354	Yes
052333188401	244111	4/14/2003 12:16:40	4SE-PICU	303479	EG7+	M51329	Yes
015389658401	236486	4/14/2003 12:12:48	6E-CVICU	301272	EG7+	M51313	Yes
002856108406	155124	4/14/2003 11:50:34	2M-RESP	302348	G3+	M51413	Yes
014204068403	342085	4/14/2003 11:40:37	3NW-CATH LAB	302045	ACT-C	M51143	Yes
002153496406	192041	4/14/2003 11:38:08	1E-PREOP	303398	G3+	M51096	Yes
051346726404	172214	4/14/2003 11:27:54	3NW-CATH LAB	302045	ACT-C	M51135	Yes
001512978414	233443	4/14/2003 11:27:03	1E-PREOP	303398	8+	M50883	Yes
000081258514	366552	4/14/2003 11:20:49	BMT-CHF	300410	E3+	M50922	Yes
015371138401	163826	4/14/2003 11:12:27	6NW-CCU2	302026	G3+	M50840	Yes
000173246401	222720	4/14/2003 10:59:24	1-STICU 2	300579	G3+	M50718	Yes
000627098409	180234	4/14/2003 10:58:56	3NW-CATH LAB	303422	ACT-C	M50776	Yes

Method: i-STAT

Viewer last updated 11Mar2004 14:10

Total results in viewer 17097

Refreshing the Data

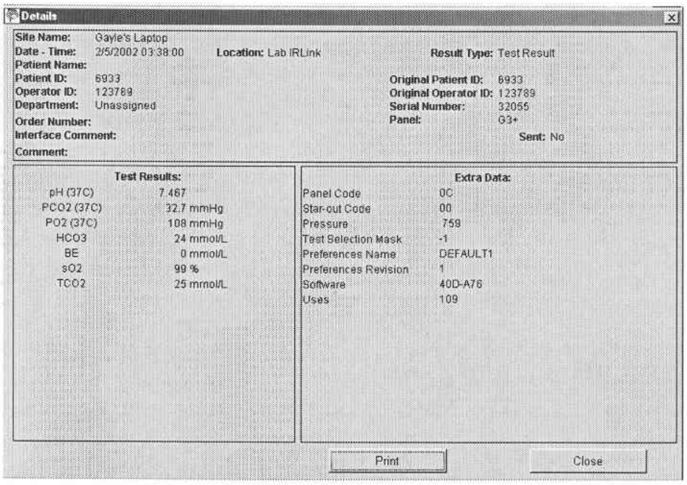
Data is received continuously by the CDS. Updating the viewers with the continuous incoming stream of data would make viewing the data difficult. Therefore, new data is not added to a viewer until the **Refresh** button is pressed. The window can also be refreshed by pressing **F5** or selecting **Refresh** from the **Window** option menu on the menu bar. The date and time of the latest refresh are listed on the bottom right of the window.

Viewing Details

The details of records in the Results, Control, Cal/Ver, Proficiency and Unsent Results Viewers can be viewed by double clicking the record, by selecting the record and clicking the **Details** toolbar button, or by selecting **Record ➪ View Details...** from the Menu.

Many of the Extra Data details may be helpful to the Customer Support representative in troubleshooting.

Example of Details for Results Viewer



Site Name: Gayle's Laptop
Date - Time: 2/5/2002 03:38:00
Location: Lab IRLink
Result Type: Test Result
Patient Name:
Patient ID: 6933
Operator ID: 123789
Department: Unassigned
Order Number:
Interface Comment:
Comment:
Original Patient ID: 6933
Original Operator ID: 123789
Serial Number: 32055
Panel: G3+
Sent: No

Test Results:	
pH (37C)	7.467
PCO2 (37C)	32.7 mmHg
PO2 (37C)	108 mmHg
HCO3	24 mmol/L
BE	0 mmol/L
sO2	99 %
TCO2	25 mmol/L

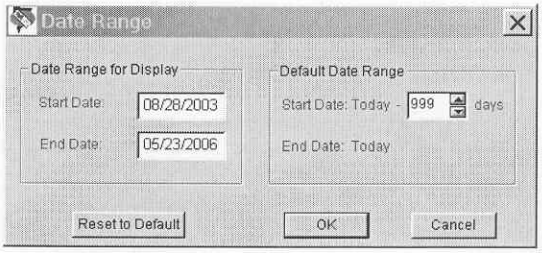
Extra Data:	
Panel Code	0C
Star-out Code	00
Pressure	759
Test Selection Mask	-1
Preferences Name	DEFAULT1
Preferences Revision	1
Software	40D-A76
Uses	109

Customizing the Data Viewers

The viewers can be customized for individual preferences. The following aspects of the viewers are user configurable.

☐ **Selecting a Date Range**

The initial default date range for data in a viewer is the current date and back 7 days. The initial default range can be changed by selecting **Tools ➪ Customize Viewer ➪ Date Range...** from the text menu, or by clicking the arrow next to the **Customize** toolbar button, then the **Date Range** button. A default date range can be set but overridden by entering a different date range for display. The maximum default date range allowed is 999 days.



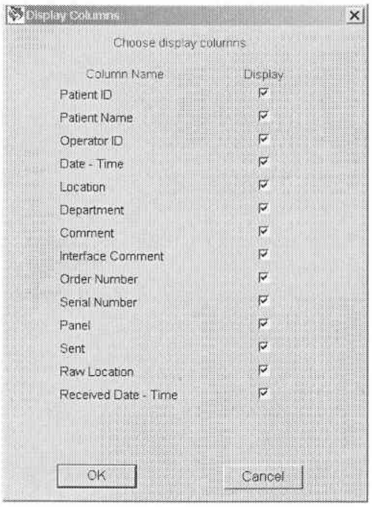
Date Range for Display
Start Date: 08/28/2003
End Date: 05/23/2006

Default Date Range
Start Date: Today - 999 days
End Date: Today

The selection of a shorter date range enhances the system performance by limiting the amount of information needing to be presented. It is always possible to expand the range to view results from earlier and then reset to a more limited default period. The date range function only limits what is presented, not what is in the database.

☐ Selecting Columns to View

Columns can be hidden. Select **Tools ➪ Customize Viewer ➪ Display Columns** or click the arrow next to the **Customize** toolbar button, then the **Columns** button. To hide a column, click the box following the column's name to uncheck it and then click **OK**. To make the column visible again, click the empty box following the column's name to check it and click the **OK** button.



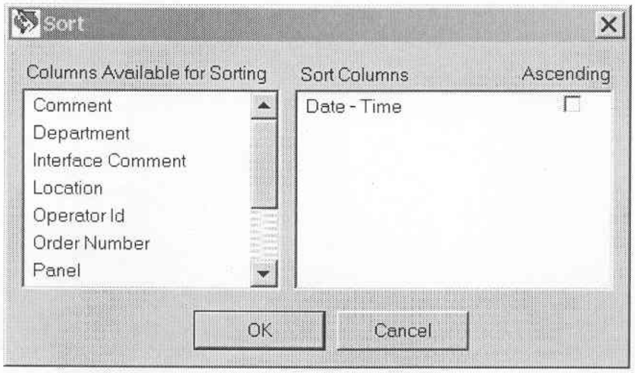
Choose display columns

Column Name	Display
Patient ID	☑
Patient Name	☑
Operator ID	☑
Date - Time	☑
Location	☑
Department	☑
Comment	☑
Interface Comment	☑
Order Number	☑
Serial Number	☑
Panel	☑
Sent	☑
Raw Location	☑
Received Date - Time	☑

The Raw Location and the Receive Date/Time columns allow users to track the location where particular analyzers are being downloaded, plus the time intervals in which users are transmitting data to the Central Data Station.

☐ Sorting Data

For customers who want to sort data in the Data Viewers by multiple column criteria, a new multilevel sorting feature has been added. To access this feature, open the desired Data Viewer, click on **Tools ➪ Customize Viewer ➪ Sort**..., or click the arrow next to the **Customize** toolbar button, then the **Sort** button.



Columns Available for Sorting:
- Comment
- Department
- Interface Comment
- Location
- Operator Id
- Order Number
- Panel

Sort Columns	Ascending
Date - Time	☐

A two-sided Sort dialog will then appear, listing **Columns Available for Sorting** on the left, and **Sort Columns** on the right. Simply click the listing under **Columns Available for Sorting** that you wish to sort your data by, and then drag that column title to the right hand side of the screen under the **Sort Columns section**. Once all of the columns you wish to sort by are under the **Sort Columns** section, check whether you want that particular column to be sorted by ascending or descending order, by placing or removing the check mark in the **Ascending** box.

Once all selections have been made, simply click on **OK** and the sort process will be completed, taking you back to the Data Viewer screen.

Note: By default, the Date/Time column is automatically placed under the **Sort Columns** section with descending order selected. If you do not wish to sort by Date/Time, simply click on that column listing and drag it back to the left side of the screen under **Columns Available For Sorting**.

Editing a Record

To edit a record, highlight the record to be edited, click **Record ➪ Edit Record** in the menu bar or click the **Edit** toolbar button.

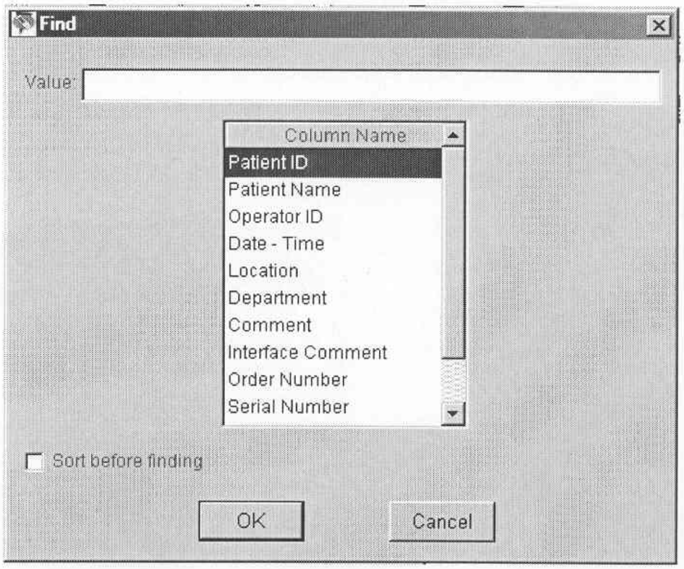
Different viewers have different editable items. Results that have been successfully sent to the LIS or HIS have only an editable Comment. Results marked as **Pending** or **In Progress** cannot be edited.

The Patient ID, Patient Name, Operator ID, Comment, Interface Comment and Order Number can be edited in the Results Viewer. Use the **Tab** key or the mouse to move across the line. The original Patient and Operator IDs will appear along with the edited IDs in the Details window.

Finding a Record

Different viewers have different lists from which to select for a search based on the data presented. Click **Record ➪ Find...** on the menu bar or click the **Find** toolbar button. Selecting **Sort before finding** before clicking **OK** will present the records in ascending order for the value after the first record matching the search is found.

Type on the Value line the desired parameter then highlight that parameter and click **OK** to find.



Printing Selected Records

With a Data Viewer open, highlight the records to be printed, click **Record ➪ Print Selected Records** or click the **Print** toolbar button.

Send Selected Records

With a Data Viewer open, highlight the records to be sent, click **Record ➪ Send Selected Records** or click the **Send** toolbar button.

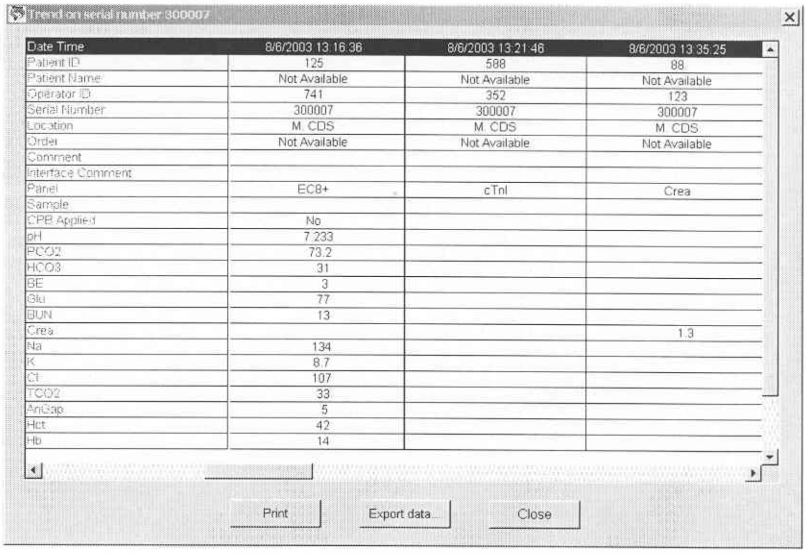
Trending Results

Results records in the Results, Control Results, Cal/Ver Results, Proficiency Results and Unsent Results Viewers can be selected for Trend reports. Trends can be performed on Patient ID, Control Lot Number, Calibration Verification Kit Number, Proficiency ID, Operator ID, Analyzer Serial Number or by a selection of records.

With the Data Viewer open, click **Record ➪ Trend,** then the trend option from the menu bar or click the arrow beside the **Trend** toolbar button and click the desired trend option. Up to 25 records are presented from oldest to newest data.

To trend by selection, highlight the records to be included in the trend report then perform the Trend function.

Example of a Result Trend by Serial Number

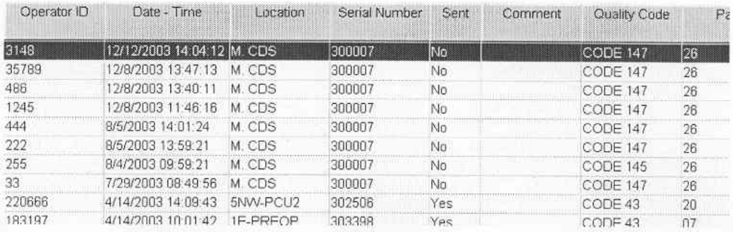


Date Time	8/6/2003 13:16:36	8/6/2003 13:21:46	8/6/2003 13:35:25
Patient ID	125	588	88
Patient Name	Not Available	Not Available	Not Available
Operator ID	741	352	123
Serial Number	300007	300007	300007
Location	M. CDS	M. CDS	M. CDS
Order	Not Available	Not Available	Not Available
Comment			
Interface Comment			
Panel	EC8+	cTnI	Crea
Sample			
CPB Applied	No		
pH	7.233		
PCO2	73.2		
HCO3	31		
BE	3		
Glu	77		
BUN	13		
Crea			1.3
Na	134		
K	8.7		
Cl	107		
TCO2	33		
AnGap	5		
Hct	42		
Hb	14		

QC Codes Viewer

All Quality Check Codes are listed in chronological order. To add a comment, click the record, then **Record ➪ Edit Record** on the menu bar or click the **Edit Record** toolbar button. To sort the Quality Check Codes by type, click the Quality Code column header. To list again in chronological order, click the Date-Time column header.

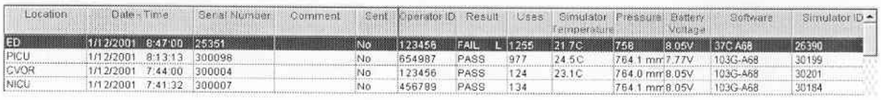
Note: Panel is a binary code for the cartridge types.



Operator ID	Date - Time	Location	Serial Number	Sent	Comment	Quality Code	Pa
3148	12/12/2003 14:04:12	M. CDS	300007	No		CODE 147	26
35789	12/8/2003 13:47:13	M. CDS	300007	No		CODE 147	26
486	12/8/2003 13:40:11	M. CDS	300007	No		CODE 147	26
1245	12/8/2003 11:46:16	M. CDS	300007	No		CODE 147	26
444	8/5/2003 14:01:24	M. CDS	300007	No		CODE 147	26
222	8/5/2003 13:59:21	M. CDS	300007	No		CODE 147	26
255	8/4/2003 09:59:21	M. CDS	300007	No		CODE 145	26
33	7/29/2003 08:49:56	M. CDS	300007	No		CODE 147	26
220666	4/14/2003 14:09:43	5NW-PCU2	302506	Yes		CODE 43	20
183197	4/14/2003 10:01:42	1E-PREOP	303398	Yes		CODE 43	07

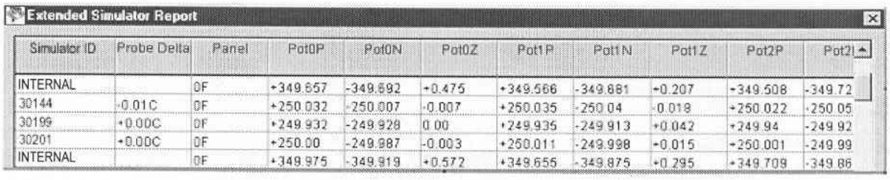
Electronic Simulator Viewer

All Electronic Simulator results, both external and internal, are listed in chronological order with the newest result at the top of the screen. To view all simulator results together for each analyzer, click the **Serial Number** column header to sort the analyzers by serial number or use the **Find...** option and sort for one analyzer. To list in chronological order again, click the **Date-Time** header.



Location	Date - Time	Serial Number	Comment	Sent	Operator ID	Result	Uses	Simulator Temperature	Pressure	Battery Voltage	Software	Simulator ID
ED	1/12/2001 8:47:00	25351		No	123456	FAIL L	1255	21.7C	758	8.05V	37C A68	26390
PICU	1/12/2001 8:13:13	300098		No	654987	PASS	977	24.5C	764.1 mm	7.77V	103G-A68	30199
CVOR	1/12/2001 7:44:00	300004		No	123456	PASS	124	23.1C	764.0 mm	8.05V	103G-A68	30201
NICU	1/12/2001 7:41:32	300007		No	456789	PASS	134		764.1 mm	8.05V	103G-A68	30184

To view the actual readings taken during the Electronic Simulator check, click **Record ➪ View Extended Simulator Report...** Note that the **Simulator ID** and **Probe Delta** columns can be viewed in the screen above by scrolling to the right.



Simulator ID	Probe Delta	Panel	Pot0P	Pot0N	Pot0Z	Pot1P	Pot1N	Pot1Z	Pot2P	Pot2
INTERNAL		0F	+349.657	-349.692	+0.475	+349.566	-349.881	+0.207	+349.508	-349.72
30144	-0.01C	0F	+250.032	-250.007	-0.007	+250.035	-250.04	-0.018	+250.022	-250.05
30199	+0.00C	0F	+249.932	-249.928	0.00	+249.935	-249.913	+0.042	+249.94	-249.92
30201	+0.00C	0F	+250.00	-249.987	-0.003	+250.011	-249.998	+0.015	+250.001	-249.99
INTERNAL		0F	+349.975	-349.919	+0.572	+349.655	-349.875	+0.295	+349.709	-349.86

Unsent Records Viewer

This viewer is available only if an external interface installed by i-STAT is enabled in the Central Data Station Customization function. This data viewer displays records that have not been sent from the Central Data Station to an external computer system, such as an LIS. The incorrect information can be corrected using **Edit** and the corrected record resent.

Unsent results can be removed from the viewer by highlighting the record, clicking on **Record ➪ Mark Selected Records as Sent,** or by pressing the **F8** Key.

Sent Column Values

Sent Column Value	Definition	Can the record be resent?
No	This is the initial value when a data record is entered into the database.	Yes
Pending	This value means that the record is in the queue waiting to be processed by the Interface.	No
In Progress	This value means that the record is currently being processed by the Interface.	No
Forwarded (HL7 Protocol Only)	This indicates that the Record has been forwarded to the receiving system but has not yet received the Application acknowledgement indicating whether or not the LIS successfully processed the record.	Yes
Yes	This value means that the i-STAT Interface application successfully processed the record. For Data File Protocol Only: • "Yes means that the Data File was successfully created in the c:\istat32\send directory. It does not necessarily mean that the record was processed by the LIS. • It is up to the receiving system to provide a status update to the CDS (See INTER32-SPC-011.doc)	No
Unsuccessful	This value means that the record send was not successful. The Interface Comment will provide some limited information as to why the record send was unsuccessful.	Yes

DATA EXPORT

A data export option is available in the following areas of the Central Data Station application:

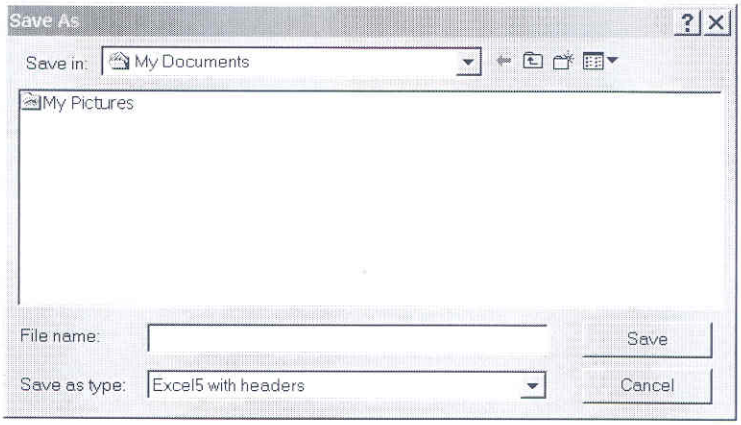
a. Data Viewers

b. Reports

c. Trend report, and

d. the Extended Simulator report screen

To access this option from any of the Data Viewers or Reports, click on **Window ➪ Export**. From a Trend report or the Extended Simulator report screen, click on the **Export data...** button at the bottom of the report. A dialog box will then appear on the screen. Choose the file destination location and the type of file you want the exported data saved as from the drop-down menus, then type in the File Name and click on Save.



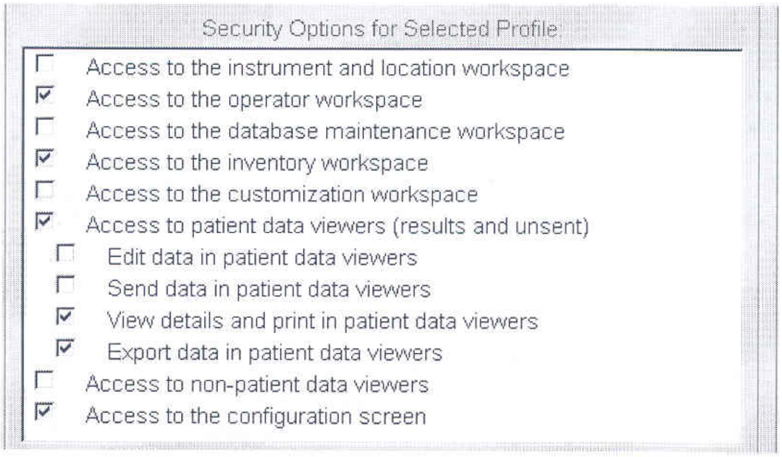
Save in: My Documents

My Pictures

File name:

Save as type: Excel5 with headers

Note: Users can be blocked from or allowed access to this data export feature through the User Administration Workspace by using the check box **"Export data in patient data viewers"** under the **Security Options for Selected Profile** section.



Security Options for Selected Profile

- ☐ Access to the instrument and location workspace
- ☑ Access to the operator workspace
- ☐ Access to the database maintenance workspace
- ☑ Access to the inventory workspace
- ☐ Access to the customization workspace
- ☑ Access to patient data viewers (results and unsent)
  - ☐ Edit data in patient data viewers
  - ☐ Send data in patient data viewers
  - ☑ View details and print in patient data viewers
  - ☑ Export data in patient data viewers
- ☐ Access to non-patient data viewers
- ☑ Access to the configuration screen

MONITORS

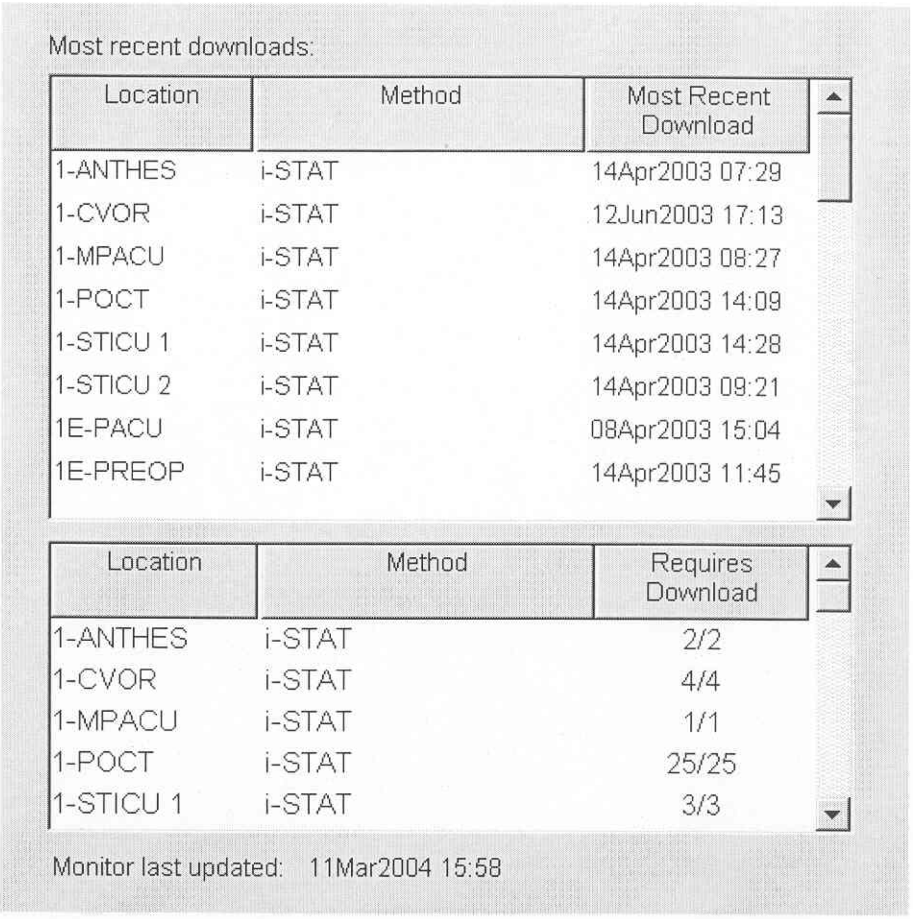
Download Monitor

The download monitor quickly identifies the download status of all locations and any locations that have instruments out of download compliance.

The upper portion of the monitor shows the last time an analyzer from the listed locations was downloaded. These columns can be sorted by clicking the column heading.

The maximum time allowed between downloads from the instrument to the CDS is defined under **Download Criteria** in the Instrument/Location workspace. The download status of each location is recorded in the Download Monitor. The **Requires Download** column indicates how many of the total number of analyzers reporting to a location have exceeded the **Download Criteria**. Clicking the location will open the Instrument and Location workspace where noncompliant analyzers will be highlighted.

The monitors are updated or refreshed according to the schedule selected during the customization of the CDS. The data can be manually refreshed by clicking the **Refresh** toolbar button or by pressing the **F5** key.



Most recent downloads:

Location	Method	Most Recent Download
1-ANTHES	i-STAT	14Apr2003 07:29
1-CVOR	i-STAT	12Jun2003 17:13
1-MPACU	i-STAT	14Apr2003 08:27
1-POCT	i-STAT	14Apr2003 14:09
1-STICU 1	i-STAT	14Apr2003 14:28
1-STICU 2	i-STAT	14Apr2003 09:21
1E-PACU	i-STAT	08Apr2003 15:04
1E-PREOP	i-STAT	14Apr2003 11:45

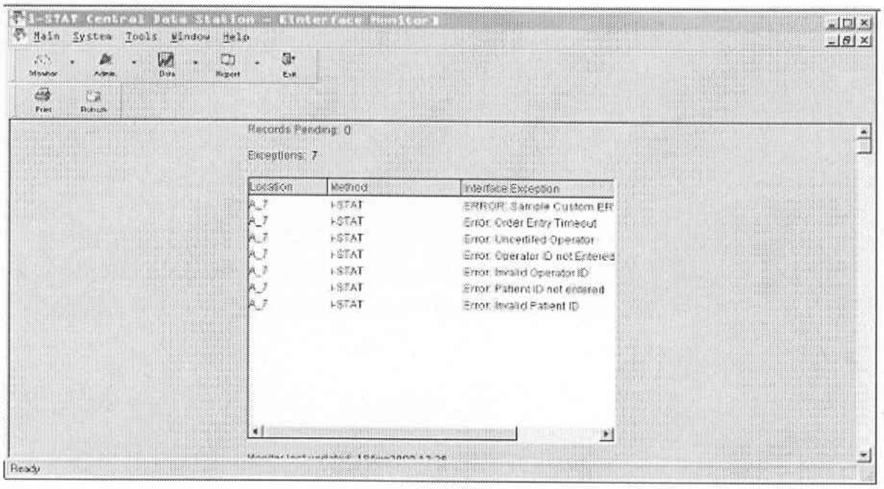
Location	Method	Requires Download
1-ANTHES	i-STAT	2/2
1-CVOR	i-STAT	4/4
1-MPACU	i-STAT	1/1
1-POCT	i-STAT	25/25
1-STICU 1	i-STAT	3/3

Monitor last updated: 11Mar2004 15:58

Interface Monitor

The Interface Monitor accessed via the menu bar functions with an interface installed by Abbott Point of Care Inc.. To access the the interface monitor for an interface installed by a third party, click on the **Interface Manager** button in the tray at the bottom of the screen.

The Interface Monitor identifies quickly the status of the Interface to an external computer. The number of pending results is shown as well as any exceptions in the last 72 hours. Clicking an exception takes you to the Unsent Results viewer to address the exception.


i-STAT Central Data Station - [Interface Monitor]
Main
System
Tools
Window
Help
Monitor
Admin.
Data
Report
Exit
Print
Refresh
Ready

Records Pending: 0

Exceptions: 7

Location	Method	Interface Exception
A_7	i-STAT	ERROR: Sample Custom ER
A_7	i-STAT	Error: Order Entry Timeout
A_7	i-STAT	Error: Uncertified Operator
A_7	i-STAT	Error: Operator ID not Entered
A_7	i-STAT	Error: Invalid Operator ID
A_7	i-STAT	Error: Patient ID not entered
A_7	i-STAT	Error: Invalid Patient ID

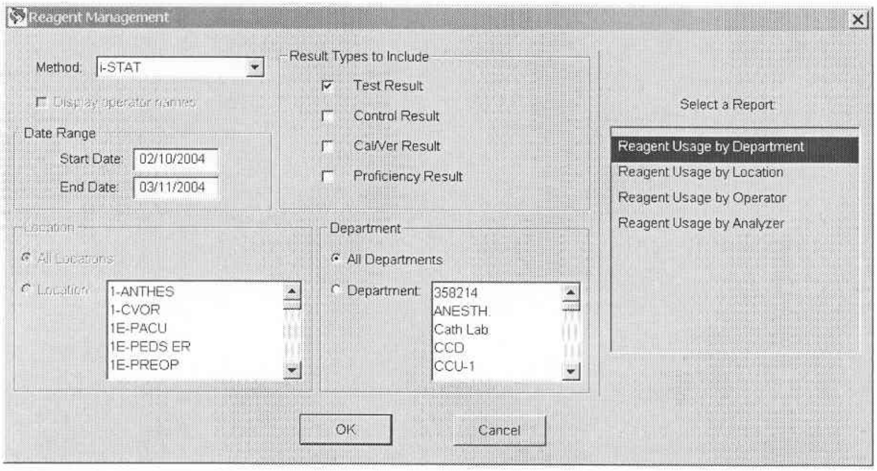
REPORTS

Overview

Reports for managing the point-of-care testing process are available from the CDS program. Three reports can be generated: Reagent Management, Method Competency and Method Compliance. These show information summarized by operator, location, department, or analyzer. Reports can be printed.

Reagent Management

This is a report of cartridge usage by Department or Location. Select a date range for the report. Data in reports, with the exception of "Operator", can be sorted by clicking on the column headers. By Operator data is pre-sorted by department. Select a report by **Reagent Usage by Department, Reagent Usage by Location**, **Reagent Usage by Operator,** or **Reagent Usage by Analyzer,** and then select either **All Locations** or **All Departments**, or select one **Location** or one **Department** from the drop down menu. Select the desired result types (Test, Control, Car/Ver, Proficiency) and then click the **OK** button.



Method: i-STAT

☐ Display operator names

Date Range

Start Date: 02/10/2004

End Date: 03/11/2004

Result Types to Include

☑ Test Result

☐ Control Result

☐ Cal/Ver Result

☐ Proficiency Result

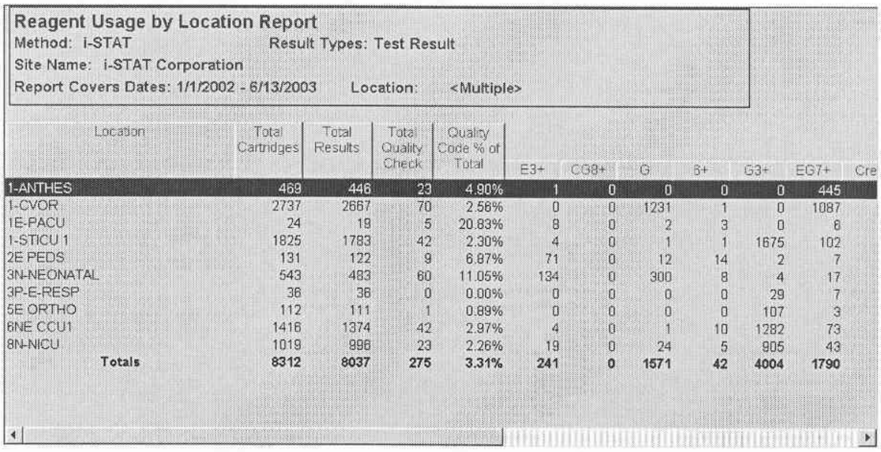
● All Locations

○ Location: 1-ANTHES, 1-CVOR, 1E-PACU, 1E-PEDS ER, 1E-PREOP

● All Departments

○ Department: 358214, ANESTH., Cath Lab, CCD, CCU-1

Reagent Usage by Department
Reagent Usage by Location
Reagent Usage by Operator
Reagent Usage by Analyzer



Reagent Usage by Location Report

Method: i-STAT Result Types: Test Result

Site Name: i-STAT Corporation

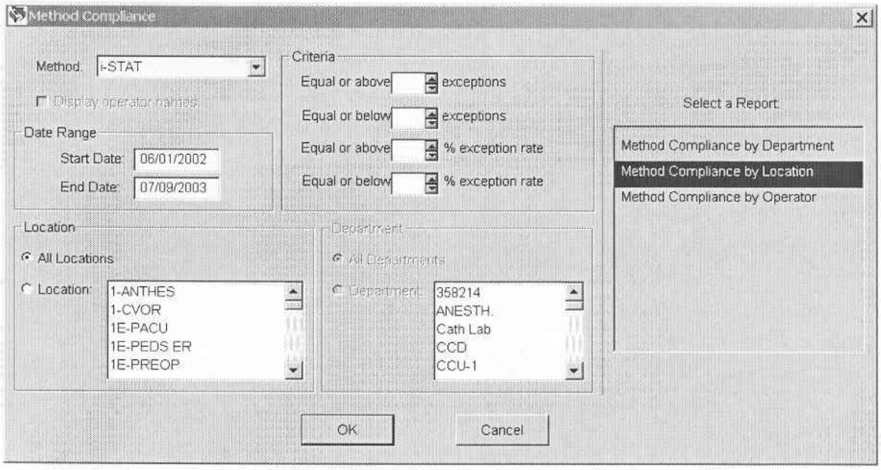
Report Covers Dates: 1/1/2002 - 6/13/2003 Location: <Multiple>

Location	Total Cartridges	Total Results	Total Quality Check	Quality Code % of Total	E3+	CG8+	G	6+	G3+	EG7+	Cre
1-ANTHES	469	446	23	4.90%	1	0	0	0	0	445	
1-CVOR	2737	2667	70	2.56%	0	0	1231	1	0	1087	
1E-PACU	24	19	5	20.83%	8	0	2	3	0	6	
1-STICU 1	1825	1783	42	2.30%	4	0	1	1	1675	102	
2E PEDS	131	122	9	6.87%	71	0	12	14	2	7	
3N-NEONATAL	543	483	60	11.05%	134	0	300	8	4	17	
3P-E-RESP	36	36	0	0.00%	0	0	0	0	29	7	
5E ORTHO	112	111	1	0.89%	0	0	0	0	107	3	
6NE CCU1	1416	1374	42	2.97%	4	0	1	10	1282	73	
8N-NICU	1019	996	23	2.26%	19	0	24	5	905	43	
Totals	**8312**	**8037**	**275**	**3.31%**	**241**	**0**	**1571**	**42**	**4004**	**1790**	

Method Compliance

This is a report of exceptions of policy and procedure for cartridge testing by Department, Location or Operator. This information is available when there is an interface to an external computer.

Select a date range for the report. Select a **Report by Department**, **Location,** or **Operator**, then select **All Locations** or **All Departments** or select one **Location** or **Department** from the list. Click on **Display operator names** if desired. When **Method Compliance by Operator** is selected, operators will be listed by department. Select the filtering criteria for the report and then click the **OK** button.


Method Compliance
Criteria
Equal or above
exceptions
Equal or below
exceptions
Equal or above
% exception rate
Equal or below
% exception rate
☐ Display operator names
Select a Report:
Method Compliance by Department
Method Compliance by Operator
Date Range
Location
○ Location:
1-ANTHES
1-CVOR
1E-PACU
1E-PEDS ER
1E-PREOP
Department
● All Departments
○ Department:
358214
ANESTH.
Cath Lab
CCD
CCU-1
OK
Cancel

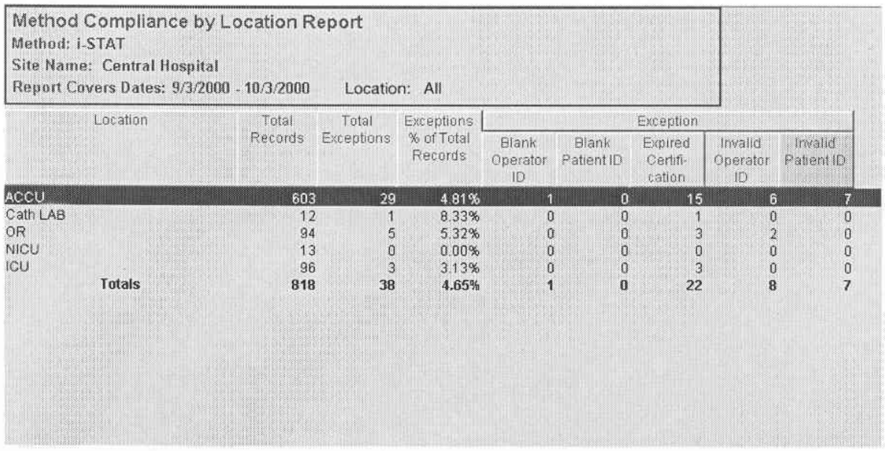
Method: i-STAT

Start Date: 06/01/2002

End Date: 07/09/2003

● All Locations

Method Compliance by Location



Method Compliance by Location Report
Method: i-STAT
Site Name: Central Hospital
Report Covers Dates: 9/3/2000 - 10/3/2000 Location: All

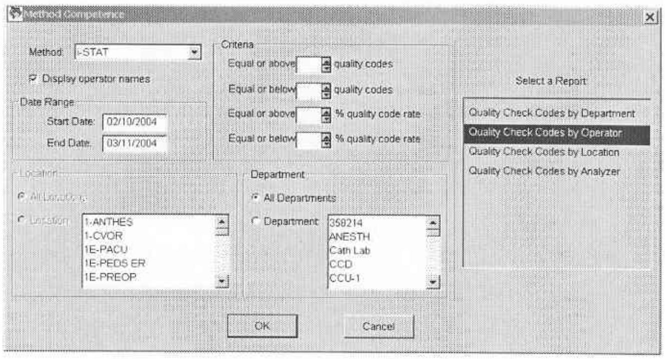
Location	Total Records	Total Exceptions	Exceptions % of Total Records	Exception				
				Blank Operator ID	Blank Patient ID	Expired Certification	Invalid Operator ID	Invalid Patient ID
ACCU	603	29	4.81%	1	0	15	6	7
Cath LAB	12	1	8.33%	0	0	1	0	0
OR	94	5	5.32%	0	0	3	2	0
NICU	13	0	0.00%	0	0	0	0	0
ICU	96	3	3.13%	0	0	3	0	0
Totals	**818**	**38**	**4.65%**	**1**	**0**	**22**	**8**	**7**

Method Competence

This is a report of Quality Check Code occurrence for cartridges by Department, Operator, Location or Analyzer.

Select a date range for the report. Select a **Report by Department**, **Location, Operator**, or **Analyzer** and then select **All Locations** or **All Departments** or select one or more **Locations** or **Departments** from the list. Click on **Display operator names** if desired. Select the filtering criteria for the report. Then click the **OK** button.

When **Quality Check Codes by Department** is selected, operators will be listed by Department.



Method Competence

Method: i-STAT

☑ Display operator names

Date Range

Start Date: 02/10/2004

End Date: 03/11/2004

Criteria

Equal or above quality codes

Equal or below quality codes

Equal or above % quality code rate

Equal or below % quality code rate

Location

○ All Locations

○ Location

Department

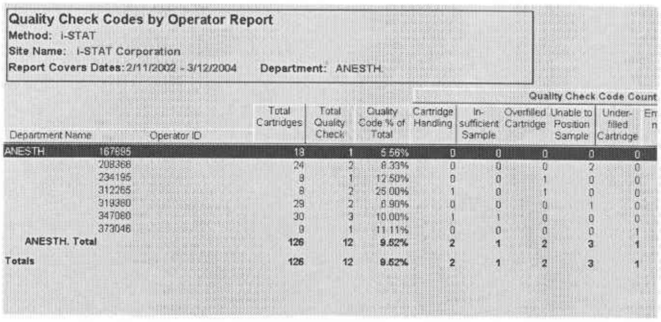
● All Departments

○ Department

Select a Report

Quality Check Codes by Operator

1-ANTHES
1-CVOR
1E-PACU
1E-PEDS ER
1E-PREOP
358214
ANESTH
Cath Lab
CCD
CCU-1
Quality Check Codes by Department
Quality Check Codes by Operator
Quality Check Codes by Location
Quality Check Codes by Analyzer
OK
Cancel



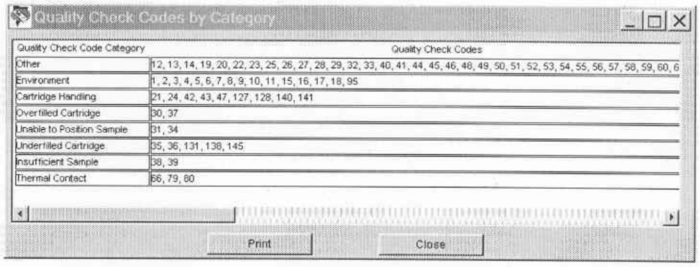
Quality Check Codes by Operator Report
Method: i-STAT
Site Name: i-STAT Corporation
Report Covers Dates: 2/11/2002 - 3/12/2004 **Department:** ANESTH

					Quality Check Code Count					
Department Name	Operator ID	Total Cartridges	Total Quality Check	Quality Code % of Total	Cartridge Handling	In-sufficient Sample	Overfilled Cartridge	Unable to Position Sample	Under-filled Cartridge	En n
ANESTH	167895	18	1	5.56%	0	0	0	0	0	
	208368	24	2	8.33%	0	0	0	2	0	
	234195	8	1	12.50%	0	0	1	0	0	
	312265	8	2	25.00%	1	0	1	0	0	
	319380	29	2	6.90%	0	0	0	1	0	
	347080	30	3	10.00%	1	1	0	0	0	
	373046	9	1	11.11%	0	0	0	0	1	
ANESTH. Total		**126**	**12**	**9.52%**	**2**	**1**	**2**	**3**	**1**	
Totals		**126**	**12**	**9.52%**	**2**	**1**	**2**	**3**	**1**	

A legend mapping individual code numbers to their respective quality check code categories is available for viewing. To access this legend:

1. Create the desired Quality Check Code report.

2. With the report still on the screen, click on **Report ➪ View QC Codes by Category...** The following dialog will appear for viewing or printing.



Quality Check Codes by Category

Quality Check Code Category	Quality Check Codes
Other	12, 13, 14, 19, 20, 22, 23, 25, 26, 27, 28, 29, 32, 33, 40, 41, 44, 45, 46, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 6
Environment	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 15, 16, 17, 18, 95
Cartridge Handling	21, 24, 42, 43, 47, 127, 128, 140, 141
Overfilled Cartridge	30, 37
Unable to Position Sample	31, 34
Underfilled Cartridge	35, 36, 131, 138, 145
Insufficient Sample	38, 39
Thermal Contact	66, 79, 80

For details of these Quality Check Codes, see the Technical Bulletin: Analyzer Coded Messages.

SYSTEM

Customization: Central Data Station Settings

Configuration of the CDS can be viewed.

Customization: i-STAT Analyzer Settings

Customization profiles of the i-STAT analyzers can be viewed.

AutoSend

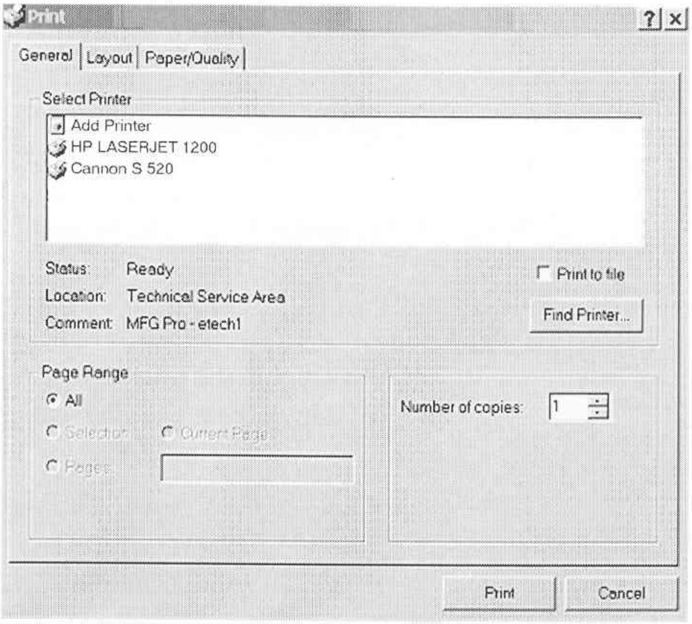
When enabled, data will be transmitted automatically from the CDS to the LIS or other information management system when received by the CDS. If AutoSend is not enabled, results can be sent to the LIS manually. Highlight the records to be sent in the appropriate Data Viewer Results viewer then click **Record ➪ Send Selected Records**. If AutoSend is enabled, it will be checkmarked under the System option on the menu bar. If an external interface is not enabled, AutoSend will appear in grey typeface.

Print Option

A Printer Dialog box has been added so that when Print is selected from the menu, the user can choose from a list of installed printers. This allows the user the option to utilize their own network printer. To access this feature, you must perform one of the following:

a. Click on **Main ➪ Print**, or

b. Click on **Records ➪ Print Selected Records**



Add Printer
HP LASERJET 1200
Cannon S 520

Status: Ready
Location: Technical Service Area
Comment: MFG Pro - etech1

☐ Print to file

Page Range
● All

Number of copies: 1

HELP

Technical Support	Phone number for your Customer Support Representative.
About...	Software version of the Central Data Station.

WINDOWS OPERATING SYSTEM AND LANGUAGE SUPPORT

Windows Version/ Service Pack	Windows Language	Supported CDS Language(s)
NT 4.0, SP6a	English	English
2000 Professional, SP4	English	English, German, Italian, Spanish, Swedish
2000 Professional, SP4	German	German, English
2000 Professional, SP4	Italian	Italian, English
2000 Professional, SP4	Spanish	Spanish, English
2000 Professional, SP4	Swedish	Swedish, English
XP Professional, SP2	English	English, German, Italian, Spanish, Swedish
XP Professional, SP2	German	German, English
XP Professional, SP2	Italian	Italian, English
XP Professional, SP2	Spanish	Spanish, English
XP Professional, SP2	Swedish	Swedish, English

During the initial installation or upgrade of the CDS 5 software, all U.S. customers should choose "English" when the language choice drop down menu appears. Failure to do so will result in the following consequences:

1. If the wrong language was chosen during the initial installation of the Version 5 software, all CDS screens will appear in the language chosen. Contact your i-STAT Support Representative if this has occurred.
2. If the wrong language was chosen during an upgrade of the CDS 5 software, the i-STAT installation instructions will appear in the language chosen, but the CDS screens will remain in English.

CARTRIDGE AND TEST INFORMATION

i-STAT sensors are available in a variety of panel configurations. Sensors are contained in cartridges with microfluidic components and, in some cartridges, calibration solution. i-STAT cartridges are used with the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer* and the Philips Medical Systems Blood Analysis Module** for the simultaneous quantitative determination of specific analytes and coagulation parameters in whole blood.

CARTRIDGE SPECIFICATIONS

Shelf Life:

Refrigerated at 2 to 8°C (35 to 46°F) until expiration date.

Room temperature at 18 to 30°C (64 to 86°F) for two weeks.

Preparation for Use:

Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour.

All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

Sample Type:

Fresh whole blood from arterial, venous, or skin punctures

(Note: Skin puncture is NOT a recommended sample type for ACT, cTnI, CK-MB, or BNP testing.)

cTnI and CK-MB cartridges require the use of heparinized whole blood or plasma, or non-heparinized whole blood tested within one minute of patient draw.

BNP cartridges require the use of EDTA whole blood or plasma samples.

Sample Volume:

17µL, 20µL, 40µL, 65µL, or 95µL depending on cartridge type.

Test Timing:

Immediately after collection

- Samples for the measurement of ACT, PT/INR and Lactate

Within 3 minutes after collection

- Samples collected in capillary tubes, both with and without anticoagulant
- Samples collected in evacuated or non-evacuated tubes and syringes without anticoagulant

Within 10 minutes after collection

- Samples collected with anticoagulant for the measurement of pH, $\boldsymbol{P}\mathrm{CO_2}$, $\boldsymbol{P}\mathrm{O_2}$ and iCa. Maintain anaerobic conditions. Remix before filling cartridge.

Within 30 minutes after collection

- Sodium, potassium, chloride, glucose, BUN/urea, creatinine, hematocrit, troponin I, CK-MB, and BNP. Remix thoroughly before testing.

Abbott
Point of Care

* The cTnI, CK-MB, and BNP cartridges can only be used with the i-STAT 1 analyzer bearing the i immuno symbol. The CHEM8+ cartridge can only be used with the i-STAT 1 analyzer.

** Blood Analysis Module supports neither the PT/INR, the CHEM8+, the cTnI, the CK-MB nor the BNP cartridge.

Analysis Time:

- ACT cartridge: to detection of end point - up to 1000 seconds (16.7 min.)
- PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- cTnI and BNP cartridges: 600 seconds (10 min.)
- CK-MB cartridge: 300 seconds (5 min.)
- Other cartridges: typically 130 to 200 seconds

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which measure ionized calcium	• Without anticoagulant • With balanced heparin anticoagulant (syringe must be filled to labeled capacity)	• Without anticoagulant • With sodium or lithium heparin anticoagulant (tubes must be filled to capacity)	• Without anticoagulant • With balanced heparin anticoagulant	• Not recommended • Not recommended for blood gas analysis; arterial specimens are preferred.
Cartridges which perform ACT	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Not recommended
Cartridges which perform PT/INR	• Without anticoagulant ONLY • Syringes must be plastic	• Without anticoagulant, clot activators, or serum separators ONLY • Tubes must be plastic • Devices used to transfer sample to cartridge must be plastic	• Not recommended	• Recommended
Cartridges which perform Troponin I or CK-MB	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw.	• With Sodium or lithium heparin anticoagulant. • Without anticoagulant if tested within one minute of patient draw. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended

Cartridges	Collection Options			
	Syringes	Evacuated Tubes	Capillary Tubes	Directly from Skin Puncture
Cartridges which perform BNP	• With EDTA anticoagulant. • Syringes must be plastic.	• With EDTA anticoagulant. • Tubes must be plastic. • Samples should not be used unless the blood collection tube is filled at least half full.	• Not recommended	• Not recommended
All other cartridges	• Without anticoagulant • With lithium, sodium, or balanced heparin anticoagulant	• Without anticoagulant • With lithium or sodium heparin anticoagulant	• Without anticoagulant • With balanced heparin anticoagulant • With sodium or lithium heparin if labeled for the measurement of electrolytes	• While a sample can be transferred directly from a skin puncture to a cartridge, a capillary tube is preferred. • Not recommended for blood gas analysis; arterial specimens are preferred.

Note Regarding System Reliability

The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Manual for detailed information). To minimize the probability of delivering a result with medically significant error the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, i-STAT recommends maintaining both a backup i-STAT System analyzer and cartridges from an alternate lot number.**

EXPECTED VALUES

Measured:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Sodium/Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
Potassium/K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Chloride/Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
Glucose/Glu	mmol/L mg/dL g/L	1.1 – 38.9 20 – 700 0.20 – 7.00	3.9 – 5.8 70 – 105 0.70 – 1.05	3.9 – 5.8 70 – 105 0.70 – 1.05
Lactate/Lac	mmol/L mg/dL	0.30 – 20.00 2.7 – 180.2	0.36 – 1.25 3.2 – 11.3	0.90 – 1.70 8.1 – 15.3

Measured: (cont.)

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Creatinine/Crea	mg/dL µmol/L	0.2 – 20.0 18 – 1768	0.6 – 1.3 53 – 115	0.6 – 1.3 53 – 115
pH		6.5 – 8.2	7.35 – 7.45	7.31 – 7.41
$P\text{CO}_2$	mmHg kPa	5 – 130 0.67 – 17.33	35 – 45 4.67 – 6.00	41 – 51 5.47 – 6.80
TCO_2 (on the CHEM8+ cartridge only)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
$P\text{O}_2$	mmHg kPa	5 – 800 0.7 – 106.6	80 – 105 10.7 – 14.0	
Ionized Calcium/iCa	mmol/L mg/dL	0.25 – 2.50 1.0 – 10.0	1.12 – 1.32 4.5 – 5.3	1.12 – 1.32 4.5 – 5.3
Urea Nitrogen/BUN **Urea**	mg/dL mmol/L mg/dL g/L	3 – 140 1 – 50 6 – 300 0.06 – 3.00	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56	8 – 26 2.9 – 9.4 17 – 56 0.17 – 0.56
Hematocrit/Hct	%PCV Fraction	10 – 75 0.10 – 0.75	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51
Celite Activated Clotting Time / $^{\text{Celite}}$ACT	seconds	50 – 1000	74 – 125 (Prewrm) 84 – 139 (Nonwrm)	74 – 125 (Prewrm) 84 – 139 (Nonwrm)

The range from 80 - 1000 seconds has been verified through method comparison studies.

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Kaolin Activated Clotting Time / $^{\text{Kaolin}}$ACT	seconds	50 – 1000	74 – 137 (Prewrm) 82 – 152 (Nonwrm)	74 – 137 (Prewrm) 82 – 152 (Nonwrm)

The range from 77 - 1000 seconds has been verified through method comparison studies.

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Prothrombin Time / PT	INR	0.9 – 8.0		

Performance characteristics have not been established for INRs above 6.0.

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Troponin I / cTnI	ng/mL (µg/L)	0.00 – 50.00		0.00 – 0.03* 0.00 – 0.08**

Performance characteristics have not been established for cTnI values above 35.00 ng/mL.
** Represents the 0 to 97.5% range of results.*
*** Represents the 0 to 99% range of results.*

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Creatine Kinase MB / CK-MB	ng/mL (µg/L)	0.0 – 150.0		0.0 – 3.5***

****Represents the 0 to 95% range of results.*

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
B-Type Natriuretic Peptide / BNP	pg/mL (ng/L)	15 – 5000		<15 – 50#

# Represents the 0 to 95% range of results.

Calculated:

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE (arterial)	REFERENCE RANGE (venous)
Hemoglobin/Hb	g/dL g/L mmol/L	3.4 – 25.5 34 – 255 2.1 – 15.8	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11
TCO_2 (on all cartridges but the CHEM8+)	mmol/L (mEq/L)	5-50	23 – 27	24 – 29
HCO_3	mmol/L (mEq/L)	1.0 – 85.0	22 – 26	23 – 28
BE	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap/AnGap	mmol/L (mEq/L)	(-10) – (+99)	10 – 20	10 – 20
sO_2	%	0 – 100	95 – 98	

CARTRIDGE CONFIGURATIONS AND SAMPLE VOLUME

i-STAT EC8$^+$ (65µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
pH
PCO_2
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
TCO_2*
HCO_3*
BE*
Anion Gap* (Angap)
Hemoglobin* (Hb)

i-STAT 6$^+$ (65µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT EC4$^+$ (65µL)

Sodium (Na)
Potassium (K)
Glucose (Glu)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT E3$^+$ (65µL)

Sodium (Na)
Potassium (K)
Hematocrit (Hct)
Hemoglobin* (Hb)

i-STAT G (65µL)

Glucose (Glu)

i-STAT CREA (65µL)

Creatinine (Crea)

i-STAT EG7$^+$ (95µL)

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT EG6$^+$ (95µL)

Sodium (Na)
Potassium (K)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT G3$^+$ (95µL)

pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*

i-STAT CG4$^+$ (95µL)

pH
PCO_2
PO_2
Lactate
TCO_2*
HCO_3*
BE*
sO_2*

**Calculated*

i-STAT CG8$^+$ (95µL)

Sodium (Na)
Potassium (K)
Ionized Calcium (iCa)
Glucose (Glu)
Hematocrit (Hct)
pH
PCO_2
PO_2
TCO_2*
HCO_3*
BE*
sO_2*
Hemoglobin* (Hb)

i-STAT CeliteACT (40µL)

Celite® ACT

i-STAT KaolinACT (40µL)

Kaolin ACT

i-STAT PT/INR (20µL)

Prothrombin Time

i-STAT cTnI (17 µL)

Troponin I

i-STAT CK-MB (17µL)

Creatine Kinase MB

i-STAT BNP (17µL)

B-type Natriuretic Peptide

i-STAT CHEM8+ (95µL)

Sodium (Na)
Potassium (K)
Chloride (Cl)
Urea Nitrogen (BUN)/Urea
Glucose (Glu)
Creatinine (Crea)
Ionized Calcium (iCa)
TCO_2
Hematocrit (Hct)
Anion Gap* (Angap)
Hemoglobin* (Hb)

Celite is a registered trademark of Celite Corporation, Santa Barbara, CA, for its diatomaceous earth products.

SODIUM/NA

Sodium is measured by ion-selective electrode potentiometry. In the calculation of results for sodium, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for sodium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of sodium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of sodium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Sodium (Na^+)

Metrological Traceability

The i-STAT System test for sodium measures sodium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Sodium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Sodium/Na	mmol/L (mEq/L)	100–180	138 – 146

*The i-STAT System can be configured with the preferred units.

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for sodium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for sodium include dehydration, diabetes insipidus, salt poisoning, skin losses, hyperaldosteronism and CNS disorders. Some causes for decreased values for sodium include dilutional hyponatremia (cirrhosis), depletional hyponatremia and syndrome of inappropriate ADH.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using NCCLS guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on NCCLS guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	120.0	0.46	0.4
Level 3	160.0	0.53	0.3

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.74	0.52	0.54
Syy	0.53	0.58	0.53
Slope	1.00	0.98	0.95
Int't	-0.11	3.57	5.26
Sy.x	1.17	1.04	1.53
Xmin	126	120	124
Xmax	148	148	148
r	0.865	0.937	0.838

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 130–150 mmol/L range the average difference was 0.750.

Factors Affecting Results*

Sodium heparin may increase sodium results up to 1mmol/L[7].

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	**Effect**
ß-hydroxybutyrate	16 mmol/L (166 mg/dL) ß-hydroxybutyrate will decrease sodium results by 5 mmol/L.
Bromide	37.5 mmol/L bromide will increase sodium results by 5 mmol/L.
Lactate	20 mmol/L lactate will decrease sodium results by 5 mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).

4. NCCLS. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* NCCLS document EP9-A [ISBN 1-56238-283-7]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. NCCLS. *Interference Testing in Clinical Chemistry; Proposed Guideline.* NCCLS document EP7-P [ISBN 1-56238-020-6]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

7. *Tips on Specimen Collection*. Vol 1. Monograph of Medical Laboratory Observer's "Tips from the Clinical Experts", published by Medical Economics in collaboration with Becton, Dickinson and Company. Mark Zacharia, ed. Montvale NJ; 1997:26.

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POTASSIUM/K

Potassium is measured by ion-selective electrode potentiometry. In the calculation of results for potassium, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for potassium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of potassium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of potassium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Potassium (K^+)

Metrological Traceability

The i-STAT System test for potassium measures potassium amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Potassium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Potassium/K	mmol/L(mEq/L)	2 – 9	3.5 – 4.9**

*The i-STAT System can be configured with the preferred units.

**The reference range for potassium listed above has been reduced by 0.2 mmol/L from the range cited in Reference 3 to account for the difference between serum and plasma results.

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for potassium in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for potassium include renal glomerular disease, adrenocortical insufficiency, diabetic ketacidosis (DKA), sepsis and in vitro hemolysis. Some causes of decreased values for potassium include renal tubular disease, hyperaldosteronism, treatment of DKA, hyperinsulinism, metabolic alkalosis and diuretic therapy.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r>0.975$.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	2.85	0.038	1.3
Level 3	6.30	0.039	0.6

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	0.060	0.031	0.065
Syy	0.055	0.059	0.055
Slope	0.97	1.06	0.99
Int't	0.02	-0.15	-0.01
Sy.x	0.076	0.060	0.112
Xmin	2.8	3.0	2.8
Xmax	5.7	9.2	5.8
r	0.978	0.993	0.948

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC4+ cartridges. In the 3.0–5.0 mmol/L range the average difference was 0.049.

Factors Affecting Results*

If heparinized whole blood is allowed to stand before testing, potassium values will first decrease slightly, then increase over time. Potassium values will increase in iced specimens.

Potassium values from anticoagulated samples are preferred to serum values because 0.1 to 0.7 mmol/L potassium can be released from platelets[1] and red blood cells during the clotting process. Potassium values obtained from skin puncture samples may vary due to hemolysis or an increase in tissue fluid from improper technique during the collection procedure.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. N.W. Tietz, E.L. Pruden, O. Siggaard-Andersen, "Electrolytes " in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, NJ: Medical Economic Books, 1987).

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5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

6. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline.* CLSI document EP7-P [ISBN 1-56238-020-6]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1986.

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CHLORIDE/CL

Chloride is measured by ion-selective electrode potentiometry. In the calculation of results for chloride, concentration is related to potential through the Nernst equation.

The i-STAT System uses direct (undiluted) electrochemical methods. Values obtained by direct methods may differ from those obtained by indirect (diluted) methods.[1]

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for chloride, as part of the i-STAT System, is intended for use in the *in vitro* quantification of chloride in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of chloride, a list of reactive ingredients is indicated below:

Reactive Ingredient
Chloride (Cl^-)

Metrological Traceability

The i-STAT System test for chloride measures chloride amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Chloride values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Chloride/CL	mmol/L(mEq/L)	65 – 140	98 – 109

*The i-STAT System can be configured with the preferred units.

The i-STAT reference range for whole blood listed above is similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Tests for chloride in the blood are important in the diagnosis and treatment of patients suffering from hypertension, renal failure or impairment, cardiac distress, disorientation, dehydration, nausea and diarrhea. Some causes of increased values for chloride include prolonged diarrhea, renal tubular disease, hyperparathyroidism and dehydration. Some causes for decreased values for chloride include prolonged vomiting, burns, salt-losing renal disease, overhydration and thiazide therapy.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.[6]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L or mEq/L)

Aqueous Control	Mean	SD	%CV
Level 1	76.7	0.54	0.7
Level 3	114.0	0.56	0.5

Method Comparison (mmol/L or mEq/L)

	Beckman Synchron CX®3	Kodak Ektachem™ 700	Nova STAT Profile® 5
n	189	142	192
Sxx	1.27	0.41	0.89
Syy	0.88	0.90	0.88
Slope	0.99	0.88	0.93
Int't	-0.82	14.6	4.3
Sy.x	1.65	1.84	2.33
Xmin	93	63	96
Xmax	114	128	117
r	0.817	0.914	0.752

Factors Affecting Results*

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	**Effect**
ß-hydroxybutyrate	16 mmol/L (166 mg/dL) b-hydroxybutyrate will increase chloride results by 3 mmol/L.
Bromide	12.5 mmol/L (100 mg/dL) bromide will increase chloride results by 30 mmol/L.
Lactate	11 mmol/L (100 mg/dL) lactate will increase chloride results by 3.5 mmol/L.
Salicylate	4 mmol/L salicylate will increase chloride results by 5 mmol/L
Thiocyanate	Thiocyanate may cause falsely elevated chloride results, or may cause chloride results to be suppressed ("star out").

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

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2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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5. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

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BUN/UREA

Urea is hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease.

$$\text{Urea} + H_2O + 2H^+ \xrightarrow{\text{urease}} 2NH_4^+ + CO_2$$

The ammonium ions are measured potentiometrically by an ion-selective electrode. In the calculation of results for urea, concentration is related to potential through the Nernst Equation.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for blood urea nitrogen (BUN/urea), as part of the i-STAT System, is intended for use in the *in vitro* quantification of BUN/urea in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of urea nitrogen, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Urea	N/A
Urease	*Canavalia ensiformis*

Metrological Traceability

The i-STAT System test for blood urea nitrogen/urea measures blood urea nitrogen/urea amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. BUN/urea values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Urea Nitrogen/BUN	mg/dL	3 – 140	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4
Urea	mg/dL	6 – 300	17 - 56
Urea	g/L	0.06 – 3.00	0.17 - 0.56

*The i-STAT System can be configured with the preferred units.

To convert a BUN result in mg/dL to a urea result in mmol/L, multiply the BUN result by 0.357. To convert a urea result in mmol/L to a urea result in mg/dL, multiply the mmol/L result by 6. To convert a urea result in mg/dL to a urea result in g/L, divide the mg/dL result by 100.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

An abnormally high level of urea nitrogen in the blood is an indication of kidney function impairment or failure. Some other causes of increased values for urea nitrogen include prerenal azotemia (e.g. shock), postrenal azotemia, GI bleeding and a high protein diet. Some causes of decreased values for urea nitrogen include pregnancy, severe liver insufficiency, overhydration and malnutrition.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.[5]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	52.8	0.76	1.4
Level 3	5.5	0.45	8.2

Method Comparison (mg/dL)

	Beckman Coulter LX20	Dade Dimension RxL-Xpand	Beckman Coulter CX9
n	39	32	26
Sxx	0.36	0.48	0.39
Syy	0.67	0.34	0.60
Slope	1.03	1.05	1.00
Int't	1.39	-0.28	-0.38
Sy.x	0.99	0.31	0.85
Xmin	5	5	7
Xmax	70	38	66
r	0.997	0.998	0.997

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT EC8+ cartridges. In the 25–60 mg/dL range the average difference was -1.13. In the 60–140 mg/dL range the average difference was -0.77.

Factors Affecting Results*

Endogenous ammonium ions will not affect results.

Interferent	**Effect**
Thiocyanate	Thiocyanate can cause falsely decreased BUN/urea results on the i-STAT System. Preliminary studies indicated that 140 mg/dL (24 mmol/L) thiocyanate decreased BUN/urea results from 11.8 to 9.3 mg/dL (4.2 to 3.3 mmol/L), approximately 21%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, *Effects of Drugs on Clinical Laboratory Tests,* 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. B.E. Statland, *Clinical Decision Levels for Lab Tests* (Oradell, NJ: Medical Economic Books, 1987).

3. CLSI. *Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Guideline.* CLSI document H7-A3 [ISBN 1-56238-413-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2001.

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5. D.S. Young and E.W. Bermes, "Influence of Site Collection on Blood Gases and pH," in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia:W.B. Saunders Company, 1994).

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GLUCOSE/GLU

Glucose is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the electrode to produce a current which is proportional to the sample glucose concentration.

$$\beta\text{-D-glucose} + H_2O + O_2 \xrightarrow{\textit{glucose oxidase}} \text{D-gluconic acid} + H_2O_2$$

$$H_2O_2 \longrightarrow 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for glucose, as part of the i-STAT System, is intended for use in the *in vitro* quantification of glucose in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of glucose, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Glucose	N/A
Glucose Oxidase	*Aspergillus niger*

Metrological Traceability

The i-STAT System test for glucose measures glucose amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Glucose values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM965. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Glucose/Glu (fasting)	mg/dL	20 – 700	70 – 105
	mmol/L	1.1 – 38.9	3.9 – 5.8
	g/L	0.20 – 7.00	0.70 – 1.05

* The i-STAT System can be configured with the preferred units.

To convert a result from mg/dL to mmol/L, multiply the mg/dL value by 0.055.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Glucose is a primary energy source for the body and the only source of nutrients for brain tissue. Measurements for determination of blood glucose levels are important in the diagnosis and treatment of patients suffering from diabetes and hypoglycemia. Some causes for increased values of glucose include diabetes mellitus, pancreatitis, endocrine disorders (e.g. Cushing's syndrome), drugs (e.g. steroids, thyrotoxicosis), chronic renal failure, stress, or I.V. glucose infusion. Some causes of decreased values of glucose include insulinoma, adrenocortical insufficiency, hypopituitarism, massive liver disease, ethanol ingestion, reactive hypoglycemia, and glycogen storage disease.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected at multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on comparative methods within 20 minutes of collection.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.[5]

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* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r > 0.975$.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	41.8	0.68	1.6
Level 3	289	2.4	0.8

Method Comparison (mg/dL)

	Beckman Coulter LX20	Bayer 860	Dade Dimension RxL-Xpand
n	35	40	32
Sxx	2.21	4.71	0.98
Syy	0.69	0.96	0.59
Slope	1.03	0.99	1.01
Int't	-3.39	-1.67	-0.85
Sy.x	0.91	0.70	1.57
Xmin	45	58	48
Xmax	297	167	257
r	0.999	0.993	0.998

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 34 patient samples using the i-STAT CHEM8+ and i-STAT CG8+ cartridges. In the 65–249 mg/dL range, the average difference was 0.80.

Factors Affecting Results*

Glucose values will decrease in whole blood samples over time. Venous blood glucose is as much as 7 mg/dL less than capillary blood glucose as a result of tissue utilization.[6]

Interferent	Effect
Bromide	37.5mmol/L (300mg/dL) bromide will decrease glucose results by 30 mg/dL.
pH	Values below 7.4 at 37°C decrease results by approximately 0.9 mg/dL (0.05 mmol/L) per 0.1 pH units. Values above 7.4 at 37°C increase results by approximately 0.8 mg/dL (0.04 mmol/L) per 0.1 pH units.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of glucose with the i-STAT System. Use an alternative method to measure glucose when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Thiocyanate	Thiocyanate can cause falsely low glucose results on the i-STAT System. Preliminary studies indicated that 24 mmol/L (140 mg/dL) thiocyanate decreased glucose results from 85.6 to 65.8 mg/dL (4.75 to 3.65 mmol/L), approximately 23%. Thiocyanate is a degradation product of nitroprusside treatment and also a product of thiosulphate treatment of cyanide poisoning.
PO_2	Oxygen levels of less than 20 mmHg (2.66 kPa) at 37°C may decrease results.

* It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, glucose will be increased by approximately 8 mg/dL (0.44 mmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the glucose level over a range of at least 75 mg/dL (4.2 mmol/L) to 645 mg/dL (35.8 mmol/L).

Ascorbic acid up to 0.63 mmol/L (11 mg/dL), uric acid up to 12 mg/dL, lactate up to 20 mmol/L (182 mg/dL), β-hydroxybutyrate up to 20 mmol/L (208 mg/dL), acetoacetate up to 10 mmol/L (100 mg/dL), acetaminophen up to 1.32 mmol/L (20 mg/dL), maltose up to 13.3 mmol/L (480 mg/dL) and hematocrit levels between 15–75 %PCV were tested and found not to interfere with glucose results.

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4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).
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HEMATOCRIT/HCT AND CALCULATED HEMOGLOBIN/HB

Hematocrit is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for hematocrit, as part of the i-STAT System, is intended for use in the *in vitro* quantification of packed red blood cell volume fraction in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution of known conductance that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for hematocrit measures packed red blood cell volume fraction in arterial, venous, or capillary whole blood (expressed as the % packed cell volume) for *in vitro* diagnostic use. Hematocrit values assigned to i-STAT's working calibrators are traceable to the U.S. National Committee for Clinical Laboratory Standards (CLSI) H7-A3 procedure for determining packed cell volume by the microhematocrit method[2]. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[3]
Hematocrit/Hct	%PCV	10 – 75	38 – 51**
	Fraction	0.10 – 0.75	0.38 – 0.51
Hemoglobin/Hb	g/dL	3.4 – 25.5	12 – 17
	g/L	34 – 255	120 – 170
	mmol/L	2.1 – 15.8	7 – 11

* The i-STAT System can be configured with the preferred units.

**The reference ranges for hematocrit and hemoglobin span both female and male populations.

To convert a result from %PCV to fraction packed cell volume, divide the %PCV result by 100. For the measurement of hematocrit, the i-STAT System can be customized to agree with methods calibrated by the microhematocrit reference method using either K_3EDTA or K_2EDTA anticoagulant. Mean cell volumes of K_3EDTA anticoagulated blood are approximately 2-4% less than K_2EDTA anticoagulated blood.[2] While the choice of anticoagulant affects the microhematocrit method to which all hematocrit methods are calibrated, results from routine samples on hematology analyzers are independent of the anticoagulant used. Since most clinical hematology analyzers are calibrated by the microhematocrit method using K_3EDTA anticoagulant, the i-STAT System default customization is K_3EDTA.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Hematocrit is a measurement of the fractional volume of red blood cells. This is a key indicator of the body's state of hydration, anemia or severe blood loss, as well as the blood's ability to transport oxygen. A decreased hematocrit can be due to either overhydration, which increases the plasma volume, or a decrease in the number of red blood cells caused by anemias or blood loss. An increased hematocrit can be due to loss of fluids, such as in dehydration, diuretic therapy, and burns, or an increase in red blood cells, such as in cardiovascular and renal disorders, polycythemia vera, and impaired ventilation.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples, collected in lithium heparin Vacutainer® tubes, were analyzed in duplicate on the i-STAT System and on the comparative methods for hematocrit within 20 minutes of collection.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-P.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (%PCV)

Whole Blood Control	Mean	SD	%CV
Low	30.0	0.44	1.5
High	49.0	0.50	1.0

Method Comparison (%PCV)

	Coulter® S Plus	Nova STAT Profile® 5	Abbott Cell-Dyn 4000	Sysmex SE9500
n	142	192	29	29
Sxx	0.50	0.46	0.41	0.53
Syy	1.09	1.31	0.77	0.76
Slope	0.98	1.06	1.06	1.11
Int't	1.78	-3.98	-1.42	-4.19
Sy.x	2.03	2.063	1.13	0.98
Xmin	18	21	19	24
Xmax	51	50	46	47
r	0.952	0.932	0.993	0.980

Factors Affecting Results*

Interferent	**Effect**
WBC	Grossly elevated white blood cell counts may increase results.
Total Protein	Hematocrit results are affected by the level of total protein as follows:

Displayed Result	TP < 6.5 g/dL	TP > 8.0 g/dL
HCT < 40 %PCV	Hct decreased by ~1% PCV for each decrease of 1 g/dL TP	Hct increased by ~1% PCV for each increase 1 g/dL TP
HCT > 40 % PCV	Hct decreased by ~0.75 % PCV for each decrease of 1 g/dL TP	Hct increased by ~0.75 %PCV for each increase 1 g/dL TP

Total protein levels may be low in neonatal and burn patient populations, as well as in additional clinical populations listed in Statland[3]. Total protein levels may also be decreased in patients undergoing cardiopulmonary bypass (CPB) or ECMO, and with patients receiving large volumes of saline-based IV fluids. Care should be taken when using hematocrit results from patients with total protein levels below the adult reference range (6.5 to 8 g/dL).

The CPB sample type can be used to correct the hematocrit result for the dilutional affect of the pump prime in cardiovascular surgery. The CPB algorithm assumes that cells and plasma are diluted equally and that the pump priming solution has no added albumin or other colloid or packed red blood cells. Since perfusion practices vary, it is recommended that each practice verify the use of the CPB sample type and the length of time in which the CPB sample type should be used during the recovery period. Note that for hematocrit values above 30 %PCV, the CPB correction is ≤1.5 %PCV; the size of the correction at this level should not impact transfusion decisions.

Lipids	Abnormally high lipids may increase results. Interference from lipids will be about two thirds the size of the interference from protein.
Sodium	The sample electrolyte concentration is used to correct the measured conductivity prior to reporting hematocrit results. Factors that affect sodium will therefore also affect hematocrit.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Sample Collection and Handling

Erroneous hematocrit results can be obtained by improper sample handling.

- Hematocrit results can be affected by the settling of red blood cells in the collection device. The best way to avoid the affect of settling is to test the sample immediately. If there is a delay in testing of a minute or more, the sample must be remixed thoroughly:
  - If the sample is in a collection tube, invert the tube gently 10 times.
  - If the sample is in a syringe, roll the syringe between the palms for five seconds in one direction, then roll in a second direction for five seconds, then gently invert repeatedly for five seconds. Note that it may not be possible to adequately mix a blood sample in a 1 mL syringe. Samples from 1 mL syringes should not be used to determine hematocrit if testing is delayed. Discard one or two drops of blood from a syringe before filling a cartridge.
- Low hematocrit results can be caused by contamination of flush solutions in an arterial or venous line.
  - Back flush a line with a sufficient amount of blood to remove intravenous solutions, heparin or medications that may contaminate the sample. Five to six times the volume of the catheter, connectors and needle is recommended.

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT 6+ and i-STAT E3+ cartridges. In the 15–30 %PCV range the average difference was 0.462. In the 30–50 %PCV range the average difference was 0.097.

Calculated Result for Hemoglobin

The i-STAT System provides a calculated hemoglobin result which is determined as follows[7]:

hemoglobin (g/dL) = hematocrit (% PCV) x 0.34

hemoglobin (g/dL) = hematocrit (decimal fraction) x 34

To convert a hemoglobin result from g/dL to mmol/L, multiply the displayed result by 0.621. The calculation of hemoglobin from hematocrit assumes a normal MCHC.

References

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IONIZED CALCIUM/ICA

Ionized calcium is measured by ion-selective electrode potentiometry. In the calculation of results for ionized calcium concentration is related to potential through the Nernst equation. Results are measured at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ionized calcium, as part of the i-STAT System, is intended for use in the *in vitro* quantification of ionized calcium in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ionized calcium, a list of reactive ingredients is indicated below:

Reactive Ingredient
Calcium (Ca^{2+})

Metrological Traceability

The i-STAT System test for ionized calcium measures ionized calcium (*i.e.* free calcium ion) amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Ionized calcium values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM956. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range[2]
Ionized Calcium/iCa	mmol/L	0.25 – 2.50	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3

*The i-STAT System can be configured with the preferred units.

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To convert a result from mmol/L to mg/dL, multiply the mmol/L value by 4. To convert mmol/L to mEq/L multiply the mmol/L value by 2.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

Although most of the calcium in blood is bound to protein or complexed to smaller anionic species, the biologically active fraction of calcium is free ionized calcium. Through its role in a number of enzymatic reactions and in membrane transport mechanisms, ionized calcium is vitally important in blood coagulation, nerve conduction, neuromuscular transmission and in muscle contraction. Increased ionized calcium (hypercalcemia) may result in coma. Other symptoms reflect neuromuscular disturbances, such as hyperreflexia and/or neurologic abnormalities such as neurasthenia, depression or psychosis. Decreased ionized calcium (hypocalcemia) often results in cramps (tetany), reduced cardiac stroke work and depressed left ventricular function. Prolonged hypocalcemia may result in bone demineralization (osteoporosis) which can lead to spontaneous fractures. Measurements of ionized calcium have proven of value under the following clinical conditions: transfusion of citrated blood, liver transplantation, open heart surgery, neonatal hypocalcemia, renal disease, hyperparathyroidism, malignancy, hypertension and pancreatitis.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[3]. Venous blood samples were collected in lithium heparin Vacutainer® tubes and analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-P.[5]

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".3 The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r>0.975$.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	1.60	0.017	1.1
Level 3	0.84	0.012	1.4

Method Comparison (mmol/L)

	Radiometer ICA1	Nova STAT Profile
n	47	57
Sxx	0.009	0.017
Syy	0.017	0.017
Slope	0.925	0.960
Int't	0.113	0.062
Sy.x	0.035	0.029
Xmin	0.46	0.53
Xmax	2.05	2.05
r	0.982	0.982

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 24 patient samples using i-STAT CHEM8+ and i-STAT CG8+ cartridges. In the 0.46 - 1.23 mmol/L range, the average difference was 0.003.

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may increase ionized calcium due to a decrease in pH caused by localized production of lactic acid[6]. Exposing the sample to air will cause an increase in pH due to the loss of CO_2 which will decrease ionized calcium.

Heparin binds calcium. Each unit of heparin added per mL of blood will decrease ionized calcium by 0.01 mmol/L.[6] Therefore, the correct ratio of heparin anticoagulant to blood must be achieved during sample collection. Intravenous injection of 10,000 units of heparin has been shown in adults to cause a significant decrease of ionized calcium of about 0.03 mmol/L.[6] Use only unheparinized sample transfer devices when using i-STAT's aqueous control and calibration verification materials.

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

Interferent	**Effect**
β-hydroxybutyrate	20 mmol/L β-hydroxybutyrate will decrease ionized calcium results by 0.1 mmol/L.
Lactate	20 mmol/L lactate will decrease ionized calcium results by 0.05 mmol/L.
Magnesium	1.0 mmol/L magnesium above normal will increase ionized calcium results by 0.04 mmol/L.
Salicylate	4.34 mmol/L salicylate will decrease ionized calcium results by 0.1 mmol/L.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

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PO_2 AND CALCULATED OXYGEN SATURATED/sO_2

PO_2 is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of oxygen partial pressure in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives.

Metrological Traceability

The i-STAT System test for oxygen partial pressure measures oxygen partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. PO_2 values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test	Units*	Reportable Range	Reference Range[2]
PO_2	mmHg	5 – 800	80 – 105
	kPa	0.7 – 106.6	10.7 – 14.0
sO_2**	%	not applicable	95 – 98

*The i-STAT System can be configured with the preferred units.

** Calculated

To convert PO_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges shown are for a healthy population. Interpretation of blood gas measurements depend on the underlying condition (eg. patient temperature, ventilation, posture and circulatory status).

Clinical Significance

PO_2 (partial pressure of oxygen) is a measurement of the tension or pressure of oxygen dissolved in blood. Some causes for decreased values of PO_2 include decreased pulmonary ventilation (e.g. airway obstruction or trauma to the brain), impaired gas exchange between alveolar air and pulmonary capillary blood (e.g. bronchitis, emphysema, or pulmonary edema), and alteration in the flow of blood within the heart or lungs (e.g. congenital defects in the heart or shunting of venous blood into the arterial system without oxygenation in the lungs).

sO_2 (oxygen saturation) is the amount of oxyhemoglobin expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin).

$$sO_2 = 100 \; \frac{(X^3 + 150X)}{X^3 + 150X + 23400}$$

$$\text{where } X = PO_2 \bullet 10^{(0.48(\text{pH}-7.4)-0.0013(\text{HCO}_3-25))}$$

However, this calculation assumes normal affinity of oxygen for hemoglobin. It does not take into account erythrocyte diphosphoglycerate (2,3-DPG) concentrations which affect the oxygen dissociation curve. The calculation also does not take into account the effects of fetal hemoglobin or dysfunctional hemoglobins (carboxy-, met-, and sulfhemoglobin). Clinically significant errors can result from incorporation of such an estimated sO_2 value for oxygen saturation in further calculations, such as shunt fraction, or by assuming the value obtained is equivalent to fractional oxyhemoglobin.

Oxygen saturation is a useful predictor of the amount of oxygen that is available for tissue perfusion. Some causes for decreased values of sO_2 include low PO_2 or impaired ability of hemoglobin to carry oxygen.

Temperature "Correction" Algorithm

PO_2 is a temperature-dependent quantity and is measured at 37°C. The PO_2 reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The PO_2 at the patient's temperature (T_p) is calculated as follows[3]:

$$PO_2(T_p) = PO_2 \times 10^{\frac{5.49\times10^{-11} PO_2^{3.88}+0.071}{9.72\times10^{-9} PO_2^{3.88}+2.30}(T_p-37)}$$

Note: Patient temperature corrected results are only available on cartridges containing pH, PCO_2, and PO_2 sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative method.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[6] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	65.1	3.12	4.79
Level 3	146.5	6.00	4.10

Method Comparison (mmHg)

	Radiometer ABL500	Radiometer ABL700	Bayer 845
n	45	29	30
Sxx	3.70	2.04	3.03
Syy	2.78	2.64	3.28
Slope	1.023	0.962	1.033
Int't	-2.6	1.2	-2.9
Sy.x	2.52	3.53	3.44
Xmin	----	39	31
Xmax	----	163	185
r	0.996	0.990	0.996

Factors Affecting Results*

Exposure of the sample to air will cause an increase in ***P*O$_2$** when values are below 150 mmHg and a decrease in ***P*O$_2$** when values are above 150 mmHg (approximate ***P*O$_2$** of room air).

Standing anaerobically at room temperature will decrease pH at a rate of 0.03 per hour, will increase ***P*CO$_2$** by approximately 4 mmHg per hour and will decrease ***P*O$_2$** at a rate of 2–6 mmHg per hour.[6]

Do not ice samples before testing – ***P*O$_2$** results may be falsely elevated in cold samples. Do not use a cold cartridge – ***P*O$_2$** results may be falsely decreased if the cartridge is cold.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Factors Affecting Calculated Results

sO$_2$ values calculated from a measured ***P*O$_2$** and an assumed oxyhemoglobin dissociation curve may differ significantly from the direct measurement.[3]

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pH

pH is measured by direct potentiometry. In the calculation of results for pH, concentration is related to potential through the Nernst equation. Results are reported at 37°C.

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for pH, as part of the i-STAT System, is intended for use in the *in vitro* quantification of pH in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of pH, a list of reactive ingredients is indicated below:

Reactive Ingredient
Hydrogen Ion (H^+)

Metrological Traceability

The i-STAT System test for pH measures the hydrogen ion amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (expressed as the negative logarithm of the relative molal hydrogen ion activity) for *in vitro* diagnostic use. pH values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference materials SRMs 186-I, 186-II, 185, and 187. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range	
pH		6.50 – 8.20	7.35 – 7.45[2] (arterial)	7.31 – 7.41* (venous)

* Calculated from Siggaard-Andersen nomogram.

Venous samples normally measure 0.01 – 0.03 pH units lower than arterial samples.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

pH is an index of the acidity or alkalinity of the blood with an arterial pH of <7.35 indicating an acidemia and >7.45 alkalemia.[3]

Temperature "Correction" Algorithm

pH is a temperature-dependent quantity that is measured on the i-STAT System at 37°C. The pH reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The pH at the patient's temperature (T_p) is calculated as follows[4]:

$$pH(T_p) = pH - 0.0147(T_p - 37) + 0.0065(7.4 - pH)(T_p - 37)$$

Note: Patient temperature corrected results are only available on cartridges containing pH, $\boldsymbol{P}CO_2$, and $\boldsymbol{P}O_2$ sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[5]. Venous blood samples were collected in evacuated tubes and arterial samples were collected in blood gas syringes with lithium heparin anticoagulant. All sample were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3 mL blood gas syringes and were analyzed in duplicate on the i-STAT-System and the comparative method within 5 minutes of each other.

Deming regression analysis[6] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data

Aqueous Control	Mean	SD	%CV
Level 1	7.165	0.005	0.08
Level 3	7.656	0.003	0.04

Method Comparison

	IL BGE	Radiometer ICA 1	Nova STAT Profile 5	Radiometer ABL500
n	62	47	57	45
Sxx	0.005	0.011	0.006	0.004
Syy	0.009	0.008	0.008	0.008
Slope	0.974	1.065	1.058	1.0265
Int't	0.196	-0.492	-0.436	-0.1857
Sy.x	0.012	0.008	0.010	0.0136
Xmin	7.210	7.050	7.050	
Xmax	7.530	7.570	7.570	
r	0.985	0.990	0.9920	.986

Factors Affecting Results*

Venous stasis (prolonged tourniquet application) and forearm exercise may decrease pH due to localized production of lactic acid. Exposing the sample to air will cause an increase in pH due to the loss of CO_2. pH decreases on standing anaerobically at room temperature at a rate of 0.03 pH units per hour.[3]

Hemodilution of the plasma by more than 20% associated with priming cardiopulmonary bypass pumps, plasma volume expansion or other fluid administration therapies using certain solutions may cause clinically significant error on sodium, chloride, ionized calcium and pH results. These errors are associated with solutions that do not match the ionic characteristics of plasma. To avoid these errors when hemodiluting by more than 20%, use physiologically balanced multi-electrolyte solutions containing low-mobility anions (e.g. gluconate) such as Normosol®-R (Abbott Laboratories), Plasma-Lyte®-A (Baxter Healthcare Corporation), and Isolyte®-S (B Braun Medical) rather than solutions such as normal saline or Ringer's Lactate.

*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

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1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

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PCO_2 AND CALCULATED VALUES FOR HCO_3, BASE EXCESS AND ANION GAP

PCO_2 is measured by direct potentiometry. In the calculation of results for PCO_2, concentration is related to potential through the Nernst equation. Results are measured at 37°C when using cartridges that require thermal control and corrected to 37°C when using cartridges that do not require thermal control.

Calculated Values

When a cartridge includes sensors for both pH and PCO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) are calculated.[1]

$\log HCO_3 = pH + \log PCO_2 - 7.608$

$BE_{ecf} = HCO_3 - 24.8 + 16.2 (pH - 7.4)$

$BE_b = (1 - 0.014{*}Hb) * [HCO_3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)]$

Anion Gap is calculated in the EC8+ and CHEM8+ catridges as follows:

$\text{Anion Gap (EC8+)} = (Na + K) - (Cl + HCO_3)$

$\text{Anion Gap (CHEM8+)} = (Na + K) - (Cl + (TCO_2 - 1))$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for PCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of carbon dioxide partial pressure in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of PCO_2, a list of reactive ingredients is indicated below:

Reactive Ingredient
Carbon Dioxide (CO_2)

Metrological Traceability

The i-STAT System test for carbon dioxide partial pressure measures carbon dioxide partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. PCO_2 values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range	
			(arterial)	(venous)
Partial Pressure Carbon Dioxide/PCO_2	mmHg	5 – 130	35 – 45[3]	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
Bicarbonate/HCO_3	mmol/L	1.0 – 85.0	22 – 26**	23 – 28**
Base Excess/BE	mmol/L	(-30) – (+30)	(-2) – (+3)[3]	(-2) – (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) – (+99)	10 – 20[3]	10 – 20[3]

*The i-STAT System can be configured with the preferred units.
**Calculated from Siggaard-Andersen nomogram.[4]

To convert PCO_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

PCO_2 along with pH is used to assess acid-base balance. PCO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. PCO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in PCO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in PCO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased PCO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at PCO_2 of 40 mmHg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Temperature “Correction” Algorithm

***P*CO$_2$** is a temperature-dependent quantity and is measured at 37°C. The ***P*CO$_2$** reading at a body temperature other than 37°C can be ‘corrected’ by entering the patient’s temperature on the chart page of the analyzer. See section 12 ‘Procedure for Cartridge Testing’ in the i-STAT 1 System Manual or section 11 ‘Patient and Control Sample Testing’ in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient’s temperature. The ***P*CO$_2$** at the patient’s temperature (T_p) is calculated as follows[1]:

$$PCO_2(T_p) = PCO_2 \times 10^{0.019(T_p - 37)}$$

Note: Patient temperature corrected results are available only on cartridges containing pH, ***P*CO$_2$**, and ***P*O$_2$** sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[5]. Venous blood samples were collected in blood gas syringes. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[6] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, “if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid”.[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.8	1.57	2.5
Level 3	19.6	0.40	2.0

Method Comparison (mmHg)

	PCO_2 IL BGE	***P***CO_2 Radiometer ABL500
n	62	29
Sxx	0.69	0.74
Syy	1.24	0.53
Slope	1.003	1.016
Int't	-0.8	1.1
Sy.x	1.65	0.32
Xmin	30.4	28
Xmax	99.0	91
r	0.989	0.999

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes ***P***CO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated. The use of partial-draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for use with the i-STAT System because of the potential for decreased measured ***P***CO_2 results and calculated HCO_3 and TCO_2 values. Under-filling blood collection tubes may also cause decreased ***P***CO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood to stand (without exposure to air) before testing allows ***P***CO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

For patients administered propofol (Diprivan®) or thiopental sodium (syn. thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[7]), i-STAT recommends the use of G3+, CG4+, CG8+, EG6+ and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol (Diprivan®) or thiopental sodium.

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* It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

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1. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* CLSI document C46-A [ISBN 1-56238-444-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

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TOTAL CARBON DIOXIDE/ (TCO_2)

Intended Use

The test for TCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of total carbon dioxide in arterial, venous, or capillary whole blood.

Method Explanation

The measured TCO_2 test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO_2 reference method[1] with an algorithm, based on the Henderson-Hasselbalch equation, which uses pH, PCO_2, and ionic strength (Na) measurements.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibration solution that contains known concentrations of analytes and preservatives. For cartridges that contains sensors for the measurement of TCO_2, a list of reactive ingredients is indicated below:

Reactive Ingredient
Carbon Dioxide (CO_2)

Metrological Traceability

The i-STAT System test for total carbon dioxide (TCO_2) measures the amount-of-substance total concentration of all forms of carbon dioxide in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. TCO_2 values assigned to i-STAT System controls and calibration verification materials are traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Measurement Procedure for Substance Concentration Determination for Total Carbon Dioxide in Blood, Plasma or Serum.[1] i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	*(venous)*
Total Carbon Dioxide/TCO_2	mmol/L	5 – 50	23 – 27*	24 – 29*

*Calculated from Siggard-Andersen nomogram.[2]

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The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender, and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, bicarbonate (HCO_3) or carbonate (CO_3) anions, and carbonic acid (H_2CO_3). Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and $\boldsymbol{P}CO_2$) and electrolyte imbalance.

Calculated and Measured (Traceable) TCO_2

The calculated TCO_2 provided by the i-STAT System is determined from the measured and reported values of pH and $\boldsymbol{P}CO_2$ according to a simplified and standardized form of the Henderson-Hasselbalch equation.[3]

$$TCO_2 = HCO_3 + 0.03\,\boldsymbol{P}CO_2$$

This calculated TCO_2 measurement is metrologically traceable to the i-STAT pH and $\boldsymbol{P}CO_2$ measurements, which are in turn traceable to primary standard reference materials for pH and $\boldsymbol{P}CO_2$. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO_2 values from the reported pH and $\boldsymbol{P}CO_2$ measurements using a combination of the equation for HCO_3 given in the $\boldsymbol{P}CO_2$ Cartridge and Test Information (CTI) sheet, and the equation for TCO_2 above.

On the CHEM8+ cartridge, TCO_2 is metrologically traceable to the IFCC TCO_2 reference method. The implication of direct traceability to this TCO_2 reference method – and not to pH and $\boldsymbol{P}CO_2$ standard reference materials – is subtle but significant: the CHEM8+ is independent of the pH and $\boldsymbol{P}CO_2$ traceability. Given the metrological traceability of the CHEM8+ TCO_2 measurement, the traceable TCO_2 is considered to be a measured analyte

Performance Characteristics

Precision data were collected in multiple sites as follows: duplicates of each control were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples were collected in lithium heparin evacuated tubes from hospital patients. The whole blood samples were run in duplicate on the i-STAT System. The samples were then centrifuged to obtain plasma and analyzed in duplicate on the comparative instrument. All samples were analyzed on both methods within 15 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set. Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables. For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and $\boldsymbol{P}CO_2$ due to loss of CO_2 during non-anaerobic handling.[6] Up to 6 mmol/L CO_2 can be lost per hour by exposure of the sample to air.[7]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid",[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method ranges in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)

Aqueous Control	**Mean**	**SD**	**%CV**
Level 1	18.2	0.21	1.2
Level 3	38.0	0.41	1.1

Method Comparison (mmol/L)

	TCO_2 **(Calculated) IL BGE**	TCO_2 **(Calculated) Beckman Coulter CX®3**	TCO_2 **(Measured) Beckman Coulter LX®20**
n	62	51	35
Sxx	0.40	0.55	0.48
Syy	0.84	0.55	0.60
Slope	1.136	1.155	1.152
Int't	-4.1	-2.6	-1.5
Sy.x	1.38	1.56	0.96
Xmin	19.3	18.3	21
Xmax	43.9	36.1	35
r	0.965	0.935	0.943

Cartridge Comparison

Performance characteristics for TCO_2 are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT CHEM8+ and i-STAT EC8+ cartridges. In the 14-30 mmol/L range, the average difference was -0.7 mmol/L.

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes TCO_2 to be under-estimated. The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for use with the i-STAT System because of the potential for decreased TCO_2 values. Under-filling blood collection tubes may also cause decreased TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood samples to stand (without exposure to air) before testing allows TCO_2 to be over-estimated, due to metabolic processes.

*It is possible that other interfering substances may be encountered.

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CREATININE/CREA

Creatinine is measured amperometrically. Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

INTENDED USE

The test for creatinine, as part of the i-STAT System, is intended for use in the *in vitro* quantification of creatinine in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of creatinine, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Creatinine	N/A
Creatine Amidinohydrolase	*Actinobacillus sp.*
Creatinine Amidohydrolase	Microbial
Sarcosine Oxidase	Microbial

Metrological Traceability

The i-STAT System test for creatinine measures creatinine amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension µmol L^{-1}) for *in vitro* diagnostic use. Creatinine values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909.

i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3[2]
	µmol/L	18 – 1768	53 – 115

To convert a creatinine result from mg/dL to µmol/L, multiply the mg/dL value by 88.4.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed. The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by professionals trained in the use of the i-STAT System and comparative methods. Clinical settings vary and some may require different performance characteristics to assess renal function status than others (e.g., medication dosing, intravenous contrast use, and outpatient clinic). If deemed necessary by a health care facility, performance data should be obtained in specific clinical settings to assure patients' needs are met.

Precision data were collected in multiple sites as follows[3]: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on CLSI guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	4.7	0.08	1.7
Level 3	0.76	0.05	6.3

Method Comparison (mg/dL)

	Roche Integra 800	Beckman LX20	J & J Vitros 950	Dade Dimension RxL
n	30	58	31	36
Sxx	0.029	0.141	0.04	0.04
Syy	0.112	0.143	0.12	0.06
Slope	0.929	0.960	0.948	0.964
Int't	0.237	0.022	0.206	0.100
Syx	0.204	0.261	0.165	0.123
Xmin	0.4	0.7	0.5	0.5
Xmax	10.3	20.0	7.2	5.7
r	0.997	0.996	0.991	0.986

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 39 patient samples using the i-STAT CHEM8+ and i-STAT Crea cartridges. In the 0.42-2.50 mg/dL range, the average difference was -0.01. In the 2.50-9.08 mg/dL range, the average difference was -0.04.

Factors Affecting Results*

Interferent	Effect
Acetaminophen	Creatinine results will increase by approximately 0.25 mg/dL (22 μmol/L) per every 1 mmol/L of acetaminophen.
Ascorbate	0.227 mmol/L ascorbate will cause a 0.7 mg/dL (62 μmol/L) increase in creatinine.
Bromide	100 mg/dL (12.5 mmol/L) bromide will increase creatinine by 0.8 mg/dL (71 μmol/L) from an initial creatinine concentration of 1.0 mg/dL (88 μmol/L).
CO_2	For Crea values below 2 mg/dL: For $\boldsymbol{P}CO_2$ values above 40 mmHg, the values are increased by 6.9% for every 10 mmHg For $\boldsymbol{P}CO_2$ values below 40 mmHg, the values are decreased by 6.9% for every 10 mmHg $[Cr]corrected = [Cr]istat \times \{1 - (0.069 \times [(PCO_2 - 40)/10])\}$ For Crea values above 2 mg/dL: For $\boldsymbol{P}CO_2$ values above 40, the values are decreased by 3.7% for every 10 mmHg For $\boldsymbol{P}CO_2$ values below 40, the values are increased by 3.7% for every 10 mmHg $Cr]corrected = [Cr]istat \times \{1 - (0.037 \times [(40 - \boldsymbol{P}CO_2)/10])\}$
Creatine	5 mg/dL (382 μmol/L) creatine will cause a 0.20 mg/dL (18 μmol/L) increase in Creatinine. For clinical situations in which creatine may be elevated, see note (1) below.

Interferent	Effect
N-acetylcysteine	16.6 mmol/L N-acetylcysteine will cause a 0.4 mg/dL (36 µmol/L) increase in creatinine.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of creatinine with the i-STAT System. Use an alternative method to measure creatinine when patients have been administered hydroxyurea. See note (2) below for typical uses of this drug and note (3) below for details of the interference.

Notes:

(1) The normal range of creatine concentration in plasma is 0.17 – 0.70 mg/dL (13 – 53 µmol/L) in males and 0.35 – 0.93 mg/dL (27 – 71 µmol/L) in females[7]. Creatine may be elevated in patients using creatine supplements, experiencing muscle trauma or other primary or secondary myopathies, taking statins for hyperlipidemia control, or in patients with hyperthyroidism or a rare genetic defect of the creatine transporter protein.

(2) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

(3) For every 100 µmol/L hydroxyurea in the whole blood sample, creatinine will be increased by approximately 1.85 mg/dL (164 µmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the creatinine level over a range of at least 1.0 mg/dL (88 µmol/L) to 12.4 mg/dL (1096 µmol/L).

Bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL (342 µmol/L), calcium up to 5.0 mg/dL (1.25 mmol/L), dopamine up to 13 mg/dL (0.85 mmol/L), methyldopa up to 2.5 mg/dL (118.4 µmol/L), salicylate up to 77.5 mg/dL (4.34 mmol/L), sarcosine up to 1.0 mmol/L, and uric acid up to 20 mg/dL (1190 µmol/L) were tested and found not to interfere with creatinine results.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

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3. CLSI. *Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline.* CLSI document EP5-A [ISBN 1-56238-368-X]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1999.

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6. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline.* CLSI document EP7-P (ISBN 1-56238-020-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1986.

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LACTATE/LAC

Lactate is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at a platinum electrode to produce a current which is proportional to the sample lactate concentration.

$$\text{L-Lactate} + O_2 \xrightarrow{\text{Lactate Oxidase}} \text{Pyruvate} + H_2O_2$$

$$H_2O_2 \xrightarrow{\text{Platinum electrode}} 2H^+ + O_2 + 2e^-$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo.*[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for lactate, as part of the i-STAT System, is intended for use in the *in vitro* quantification of lactate in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of lactate, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Lactate	N/A
Lactate Oxidase	*Aerococcus viridans*

Metrological Traceability

The i-STAT System test for lactate measures L-lactate amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. Presently, no international conventional reference measurement procedure or international conventional calibrator for lactate is available. Lactate values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from sodium L-lactate (Sigma-Aldrich Fluka, >99 % purity). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference[2] Range (arterial)	Reference[2] Range (venous)
Lactate/Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3

To convert a lactate result from mmol/L to mg/dL, multiply the mmol/L value by 9.01.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolumia, and left ventricular failure; in conditions associated with diseases such as diabetes mellitus, neoplasia, and liver disease; and in conditions associated with drugs or toxins such as ethanol, methanol, or salicylates.[2]

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected using CLSI guideline EP5-A[3]. Duplicates of each level of control were tested on three lots of cartridges over 20 days for a total of 120 replicates.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples, collected in sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. In the plasma study, a portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on CLSI guideline EP7.[6]

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[3] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if $r>0.975$.

Precision Data (mmol/L)	Aqueous Control	n	Mean	SD	%CV
	Level 1	120	6.35	0.08	1.21
	Level 3	120	0.81	0.03	3.27

Method Comparison (mmol/L)	Radiometer ABL 725 **(whole blood vs. whole blood)**	Hitachi 917 **(i-STAT whole blood vs. Hitachi plasma)**
n	47	47
Sxx	0.123	0.084
Syy	0.136	0.079
Slope	1.02	1.06
Int't	0.12	-0.32
Sy.x	0.18	0.17
Xmin	0.80	1.77
Xmax	14.20	14.24
r	0.998	0.997

Factors Affecting Results*

Special collection procedures are necessary to prevent changes in lactate both during and after the blood is drawn. For steady state lactate concentrations, patients should be at rest for 2 hours and fasting. Venous samples should be obtained without the use of a tourniquet or immediately after the tourniquet is applied. Both venous and arterial samples may be collected into heparinized syringes.

Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25 °C as a result of glycolysis.[2]

Interferent	**Effect**
Bromide	25 mmol/L (200 mg/dL) bromide will decrease lactate results by 40%.
Cysteine	6.4 mmol/L (101 mg/dL) cysteine will decrease lactate results by 11%.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of lactate with the i-STAT System. Consider using an alternative method to measure lactate when patients have been administered hydroxyurea. See note (1) below for typical uses of this drug and note (2) below for details of the interference.
Glycolic Acid:	Glycolic acid can cause falsely increased lactate results on the i-STAT System. Preliminary studies indicated that 10 mmol/L glycolic acid increased lactate from 1.45 mmol/L to 3.41 mmol/L. See note (3) for details.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Notes:

1) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

2) For every 100 µmol/L hydroxyurea in the whole blood sample, lactate will be increased by approximately 0.16 mmol/L, up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the lactate level over a range of at least 2.8 mmol/L to 16.0 mmol/L.

3) Glycolic acid is a product of ethylene glycol metabolism. Unexpected increased lactate concentrations caused by glycolic acid may be a clue to the possibility of ethylene glycol ingestion as the cause of an otherwise unknown high anion gap metabolic acidosis.[7,8] In a study of 35 patients who had ingested ethylene glycol, initial glycolic acid concentrations of 0 to 38 mmol/L corresponded to ethylene glycol levels of 0.97 - 130.6 mmol/L.[7]

Acetaldehyde up to 0.6 mg/dL (0.14 mM), acetominophen up to 20 mg/dL (1.3 mM), acetylsalicylic acid up to 50 mg/dL (2.8 mM), ascorbic acid up to 3 mg/dL (0.17 mM), ß-hydroxybutyric acid up to 202 mg/dL (16 mM), dopamine up to 13 mg/dL (0.85 mM), formaldehyde up to 1.2 mg/dL (0.40 mM), glycine up to 98 mg/dL (13 mM), pyruvic acid up to 2.6 mg/dL (0.24 mM), and uric acid up to 25 mg/dL (1.5 mM) were tested and found not to interfere with lactate results. Hematocrit levels between 25 and 67% were tested and found not to interfere with lactate results.

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CELITE ACTIVATED CLOTTING TIME/ (CELITEACT)

The i-STAT® Celite® Activated Clotting Time test, ^{Celite}ACT, is a measure of the time required for complete activation of the coagulation cascade.[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT ^{Celite}ACT test is similar to traditional ACT tests except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- $NH - C_6H_4 - NH - C_6H_4 - OCH_3$

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound $NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3$. The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) as a whole blood time (WBT) in seconds.

The i-STAT ^{Celite}ACT test is calibrated to match the Hemochron Celite FTCA510 using prewarmed tubes. However, users of the i-STAT®1 analyzer may choose to customize their individual i-STAT locations to report ACT results as calibrated against the Hemochron Celite ACT using non-prewarmed (ambient) temperature tubes. This customization affects the Patient path only, and will not be applied to the Control or the Proficiency Testing pathway.

The customization in effect (prewarm or non-prewarm calibration mode) is identified on the analyzer screen as PREWRM or NONWRM, respectively. Please note that different locations within a given hospital may utilize different customization profiles. Prior to patient sample testing, ensure the appropriate calibration mode is employed. For a comprehensive discussion of this customization feature, please see the Technical Bulletin entitled "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer".

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Celite Activated Clotting Time (^{Celite}ACT) test cartridge, as part of the i-STAT System, is an *in vitro* diagnostic test used to monitor moderate- and high-level heparin therapy through analysis of arterial and venous whole blood samples.

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Contents

Each i-STAT $^{\text{Celite}}$ACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint, and dry reagents necessary to initiate and allow coagulation. Stabilizers and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient
Diatomaceous Earth
Thrombin Substrate

Metrological Traceability

The i-STAT System test for Celite Activated Clotting Time measures the time interval required for complete activation, by Celite®, of the coagulation cascade in arterial or venous whole blood (dimension seconds) for *in vitro* monitoring of moderate- and high-level heparin therapy. Presently, no international conventional reference measurement procedure or international conventional calibrator for $^{\text{Celite}}$ACT is available. $^{\text{Celite}}$ACT values assigned to i-STAT's controls are traceable to i-STAT's selected reference measurement procedure, which employs diatomaceous earth (Celite) activated glass reagent tubes, an automated timer and traditional viscometric clot detection and is run under specified temperature and sample conditions. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (PREWRM)	Reference Range (NONWRM)
Activated Clotting Time/ACT	seconds	50 - 1000*	74 - 125	84 - 139

*The range from 80 - 1000 seconds has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods. All data uses the PREWRM calibration, unless otherwise noted.

Precision data were collected at Abbott Point of Care Inc. and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	329	221 seconds	18 seconds	8.1
Level 2	438	456 seconds	22 seconds	4.8

Method comparison data were collected using a modification of the CLSI guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used. This includes baseline, heparin-treated, and heparin-reversed samples from from patients undergoing cardiac catheterization and cardiac bypass.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

Cath Lab	Medtronic HR-ACT	Hemochron CA510/FT CA510
n	270	418
Sxx	10.1	19.7
Syy	10.7	13.5
Slope	1.15	0.86
Int't	-30	-3
Sy.x	32.5	22.5
Xmin	73	63
Xmax	523	763
r	0.848	0.903

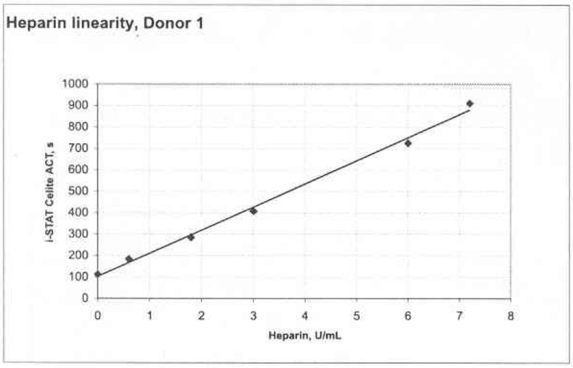
	Hemchron CA510/FT CA510		
CVOR	Site 1	Site 2	Site 3
n	35	30	24
Sxx	15.8	34.2	24.4
Syy	13.0	11.5	20.8
Slope	0.85	1.10	1.19
Int't	4	-52	-73
Sy.x	43.8	17.4	62.1
Xmin	118	94	125
Xmax	671	735	767
r	0.912	0.952	0.891

Factors Affecting Results*

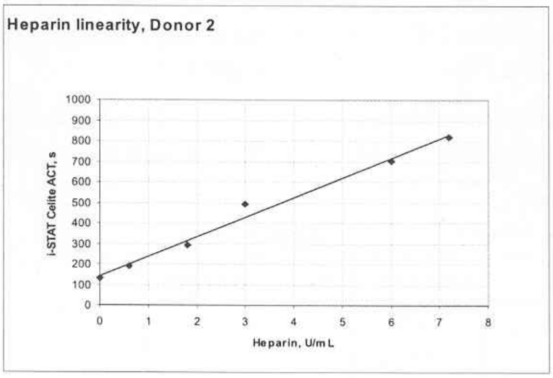
*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

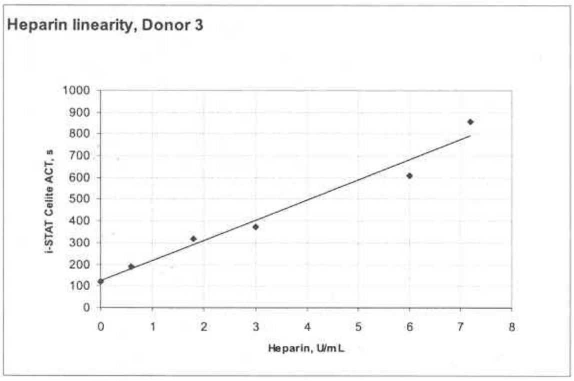
The five graphs below each indicate the response of a different donor with respect to heparin concentration:



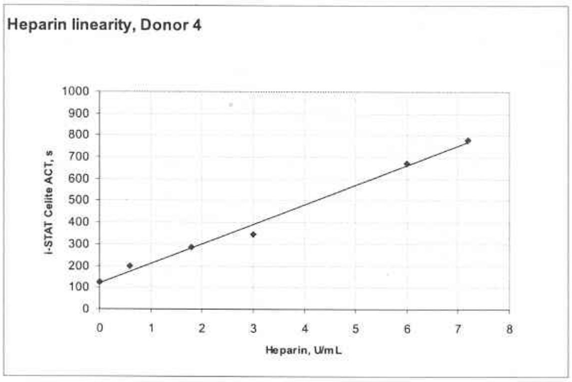
Heparin linearity, Donor 1



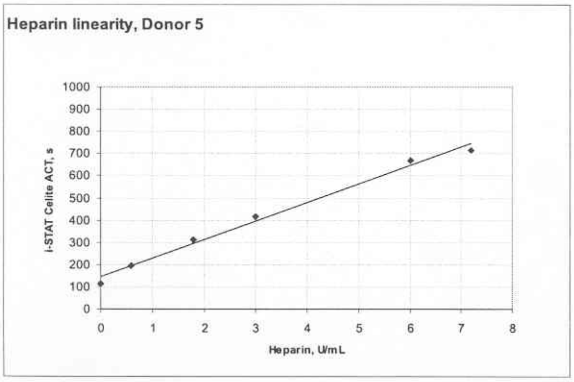
Heparin linearity, Donor 2



Heparin linearity, Donor 3

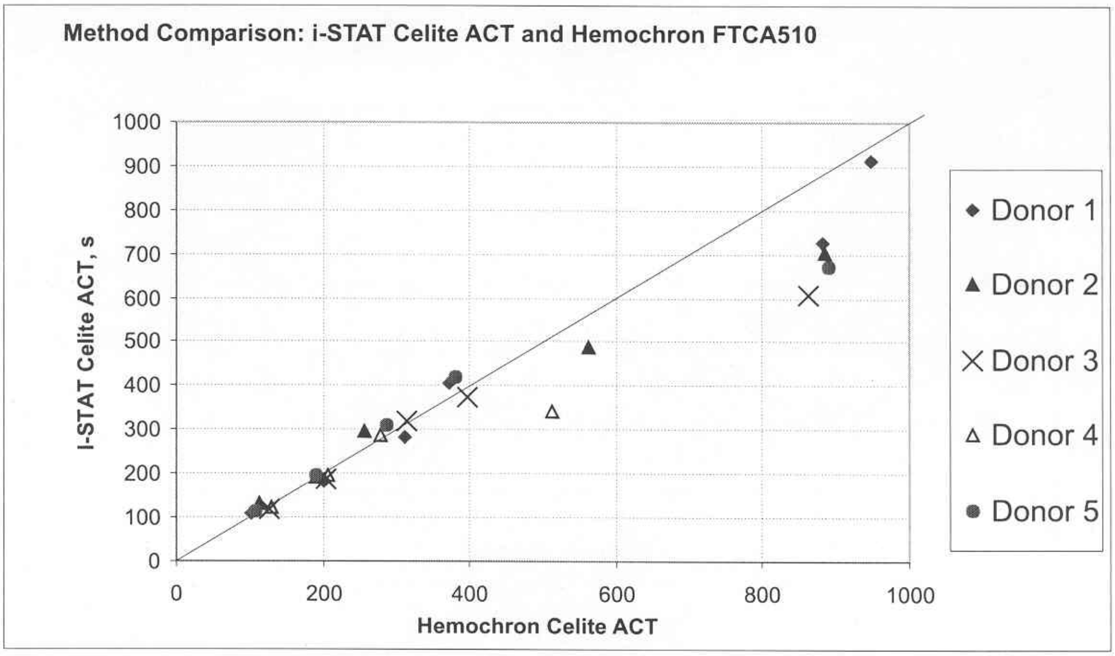


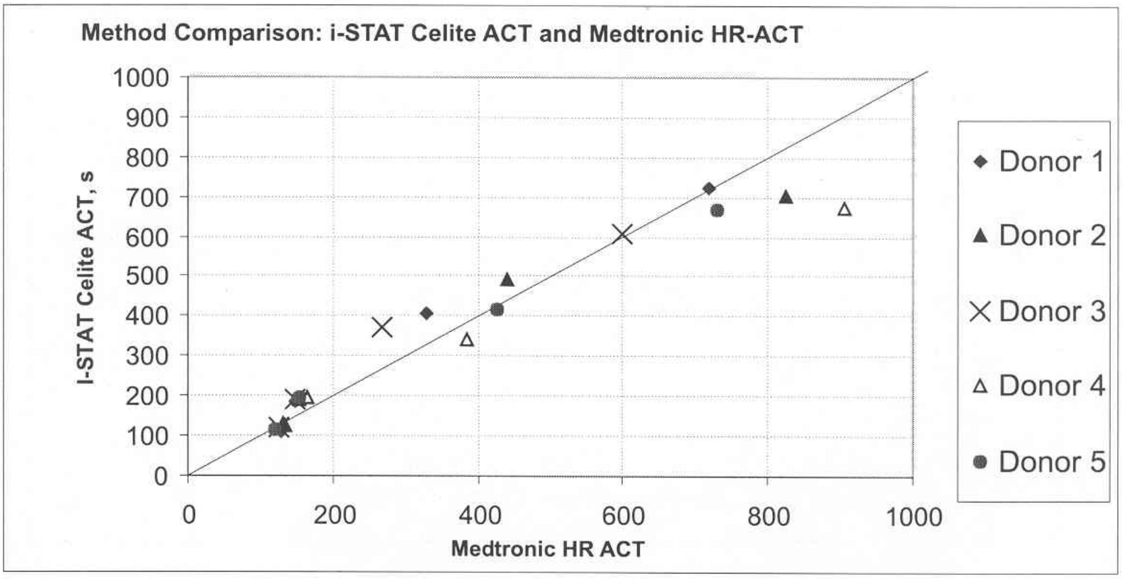
Heparin linearity, Donor 4



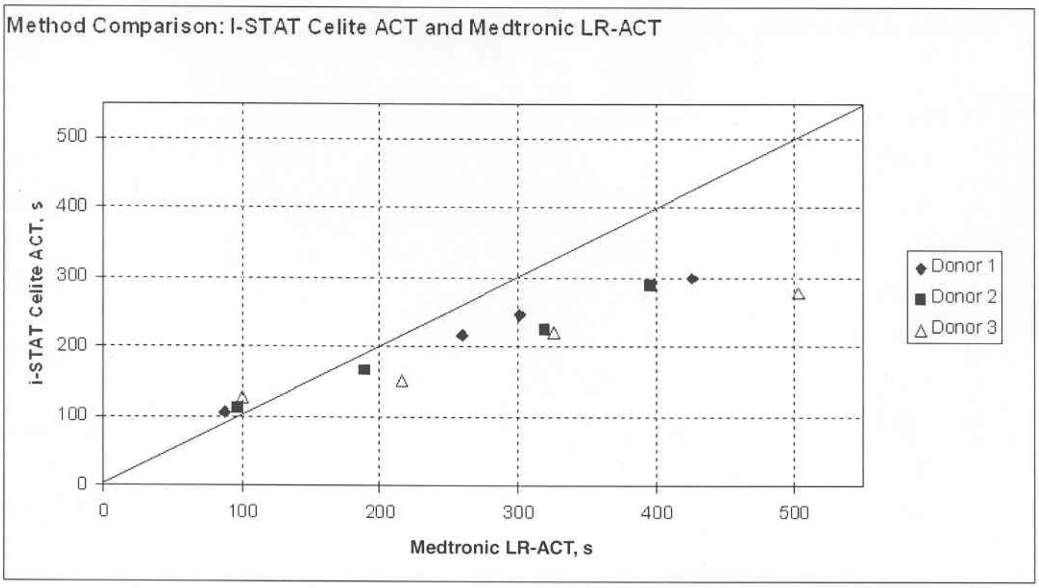
Heparin linearity, Donor 5

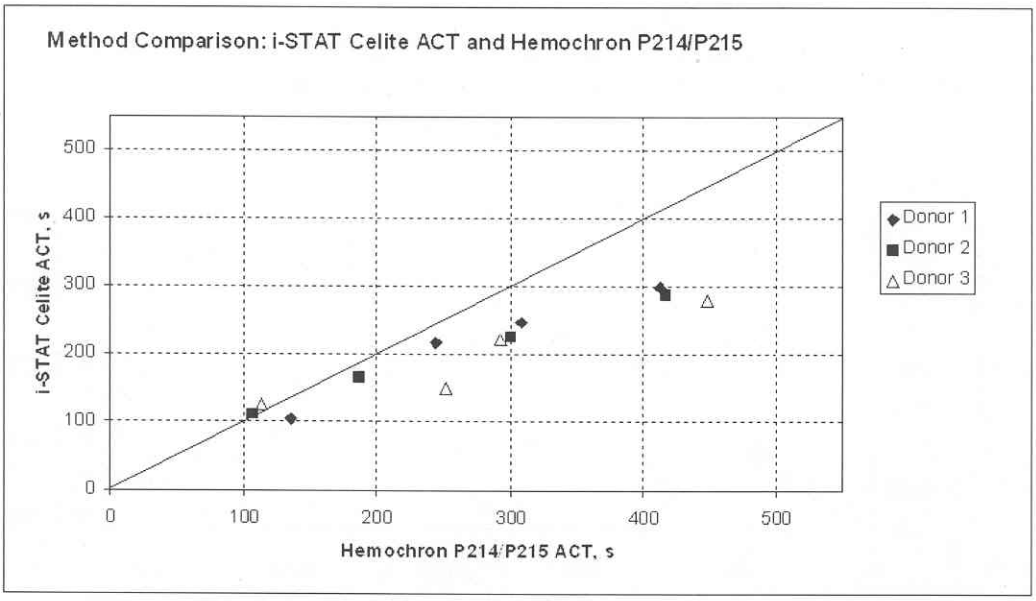
The graphs below indicate the response of the same five donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Celite FTCA 510.





Performance of the i-STAT Celite ACT at lower levels of heparin is shown below with two "Low Range" ACT methods included for comparison:





Test Limitations

The i-STAT $^{\text{Celite}}$ACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The i-STAT ACT test uses Celite brand diatomaceous earth as the activator of the intrinsic pathway. The result may, therefore, be prolonged in the presence of aprotinin.[4] **The test is not recommended for use with patients receiving aprotinin.**

The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%.

Hemodilution may affect test results.

Platelet dysfunction, factor deficiencies, dysprothrombinemias, pharmacological compounds, and other coagulopathies may affect the results of this test.

The i-STAT ACT test is not affected by hematocrit in the range of 20 - 70%, fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37°C.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperature was satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT ACT Controls using any verified Analyzer. Instructions for the use of these controls are found in the i-STAT System Manual.

For additional information on Quality Control of the i-STAT System, refer to the Quality Control section in the i-STAT System Manual.

Specimen Collection and Preparation

The i-STAT $^{\text{Celite}}$ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[5]

In-dwelling line

- Fluid drip through the line must be discontinued.
- Withdraw 2 mL of blood into a syringe and discard it.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

1. Hattersly, P. Activated coagulation time of whole blood. Journal of the American Medical Association 136:436-440, 1966.

2. CLSI. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. CLSI document EP9-A (ISBN 1-56238-283-7). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.

3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Wang, JS; Lin, CY; Hung, WT; Thisted, RA; Carp, RB. In vitro effects of aprotinin on activated clotting time measured with different activators. Journal of Thoracic Cardiovascular Surgery 104(4):1135-40, 1992.

5. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

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KAOLIN ACTIVATED CLOTTING TIME/ (KAOLINACT)

The i-STAT® Kaolin Activated Clotting Time test, KaolinACT, is a measure of the time required for complete activation of the coagulation cascade.[1]

In traditional ACT tests, coagulation is initiated by mixing a whole blood sample with a particulate activator, and complete activation is indicated when extensive or localized clots form as activated thrombin converts fibrinogen to fibrin. These clots are mechanically detected.

The i-STAT KaolinACT test is similar to traditional ACT tests except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen and an electrochemical sensor is used to indicate the event of this conversion. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen.

The substrate is H-D-phenylalanyl-pipecolyl-arginine-*p*-amino-*p*-methoxydiphenylamine which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy- terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3. The formation of the electroactive compound is detected amperometrically, and the time of detection is measured in seconds. The test reports the Activated Clotting Time (ACT) in seconds.

The i-STAT KaolinACT test is calibrated to match the Hemochron Celite FTCA510 using prewarmed reagent tubes. However, users of the i-STAT®1 analyzer may choose to customize their individual i-STAT locations to report ACT results as calibrated against the Hemochron Celite ACT using non-prewarmed (ambient temperature) tubes. This customization affects the Patient path only, and will not be applied to the Control or the Proficiency Testing pathway.

The customization in effect (prewarm or non-prewarm calibration mode) is identified on the analyzer screen as PREWRM or NONWRM, respectively. Please note that different locations within a given hospital may utilize different customization profiles. Prior to patient sample testing, ensure the appropriate calibration mode is employed. For a comprehensive discussion of this customization feature, please see the Technical Bulletin entitled "ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer".

If results appear inconsistent with the clinical assessment, the patient sample should be re-tested using another cartridge.

Intended Use

The i-STAT Kaolin Activated Clotting Time (KaolinACT) test is an *in vitro* diagnostic test that uses fresh whole blood to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.

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The test is to be used with the i-STAT Portable Clinical Analyzer and the i-STAT 1 Analyzer, but not the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM).

Contents

Each i-STAT ^{Kaolin}ACT cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint, and dry reagents necessary to initiate and allow coagulation. Stabilizers and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient
Kaolin
Thrombin Substrate

Metrological Traceability

The i-STAT System test for Kaolin Activated Clotting Time measures the time interval required for complete activation, by kaolin, of the coagulation cascade in arterial or venous whole blood (dimension seconds) for *in vitro* monitoring of high-level heparin therapy. Presently, no international conventional reference measurement procedure or international conventional calibrator for ^{Kaolin}ACT is available. ^{Kaolin}ACT values assigned to i-STAT's controls are traceable to i-STAT's selected reference measurement procedure, which employs Celite activated glass reagent tubes, an automated timer and traditional viscometric clot detection and is run under specified temperature and sample conditions. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Reportable Range	Reference Range (PREWRM)	Reference Range (NONWRM)
Activated Clotting Time/ACT	seconds	50 - 1000*	74 - 137	82- 152

*The range from 77 - 1000 seconds (PREWRM mode) has been verified through method comparison studies.

Clinical Significance

The ACT is primarily used to monitor a patient's state of anticoagulation due to heparin that is administered during a medical or surgical procedure. It is commonly employed in cardiac catheterization, Percutaneous Transluminal Coronary Angioplasty (PTCA), renal dialysis, hemodialysis, and extra-corporeal circulation during bypass.

Performance Characteristics

The typical performance data summarized below was collected in health care facilities by health care professionals trained in the use of the i-STAT System and comparative methods. All data uses the PREWRM calibration, unless otherwise noted.

Precision data were collected at i-STAT and during clinical trials following a protocol recommended by i-STAT and using plasma control material. Similar results can be expected in future performance studies provided the same experimental design and data analysis procedures are followed.

Plasma Control	n	Mean	SD	%CV
Level 1	119	169 seconds	4 seconds	2.0
Level 2	113	409 seconds	21 seconds	5.2

Method comparison data were collected using a modification of the CLSI guideline EP9-A[2]. Venous or arterial blood samples were collected in plastic syringes and analyzed in duplicate on the i-STAT System and in duplicate using the comparative methods. All samples were analyzed immediately upon collection. The patient populations in the studies were those in which ACT is routinely used and included both aprotinin and non-aprotinin receiving patients. All were undergoing cardiac surgery. Sample types included baseline, heparin-treated, and heparin-reversed samples.

Deming regression analysis[3] was performed on the first replicate of each sample. In the method comparison table, *n* is the number of specimens in the data set, *Sxx* and *Syy* refer to estimates of the imprecision based on the duplicates of the comparative and i-STAT methods respectively, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables.

	Hemochron FTK-ACT		
CVOR	**Site 1**	**Site 2**	**Site 3**
n	104	118	106
Sxx	9.1%	6.8%	7.6%
Syy	3.6%	4.0%	3.6%
Slope	0.96	1.05	0.96
Intercept	-12	-38	-39
Xmin	68	111	81
Xmax	1286	1310	1102
r	0.906	0.940	0.971

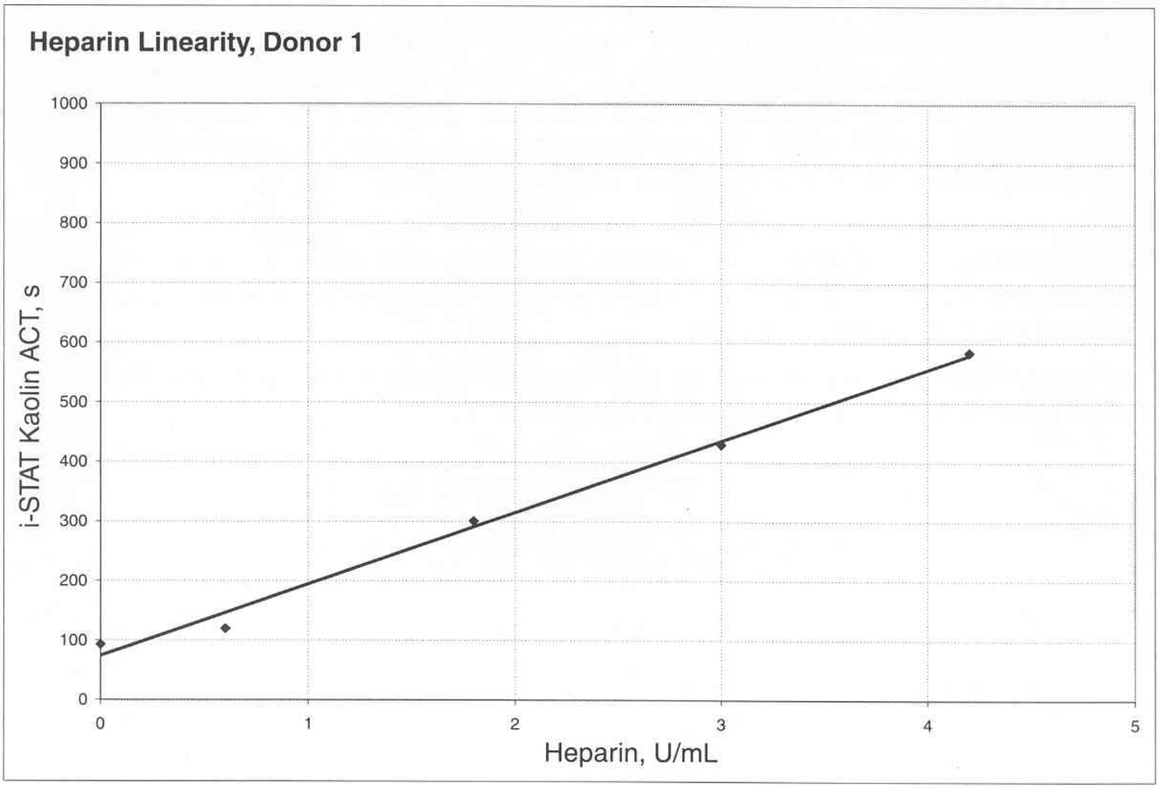
Factors Affecting Results*

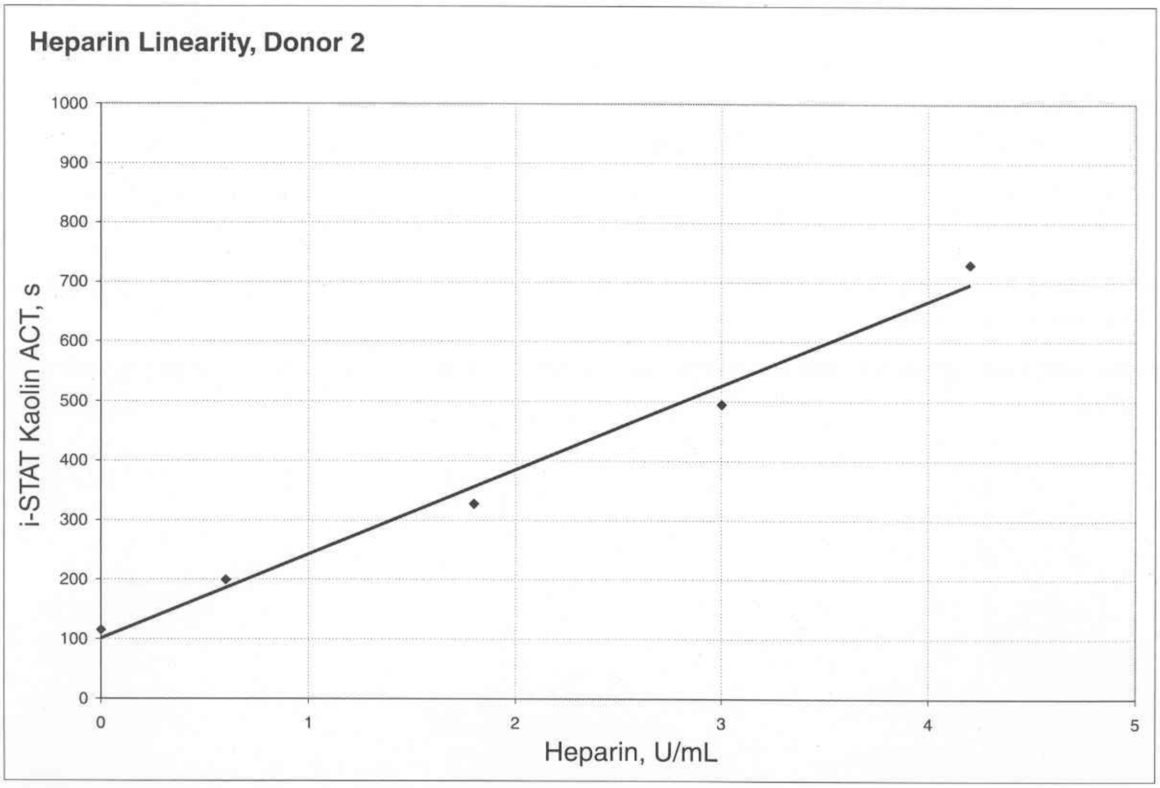
The i-STAT ^{Kaolin}ACT test is not significantly prolonged in the presence of aprotinin (Trasylol).

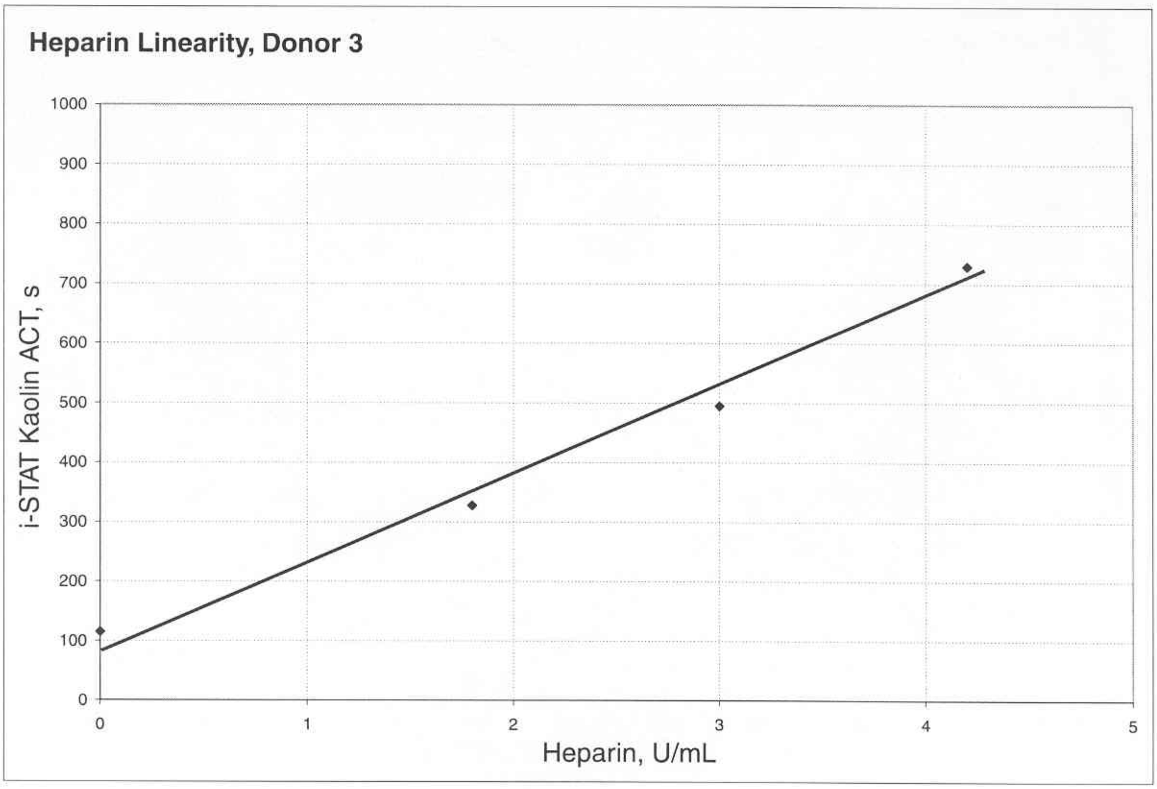
*It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Heparin sensitivity was demonstrated using whole blood samples to which varying concentrations of heparin were added *in vitro*.

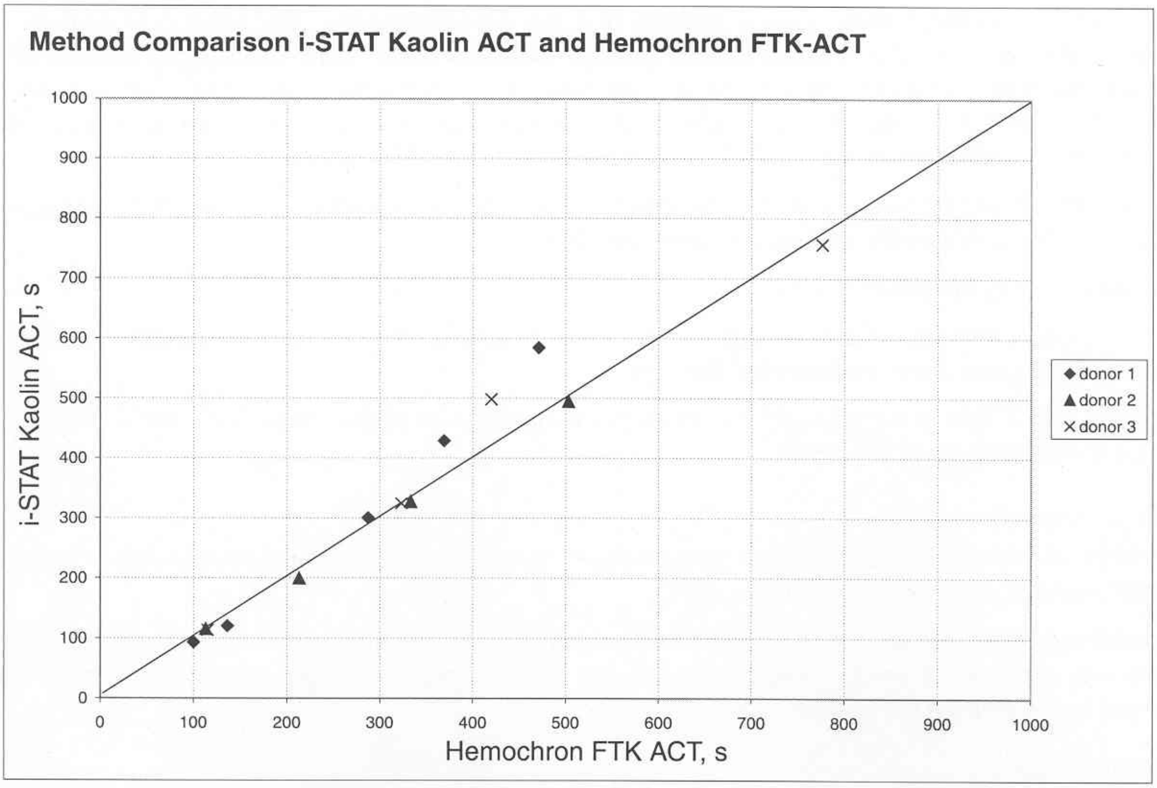
The following three graphs below each indicate the response of a different donor with respect to heparin concentration:

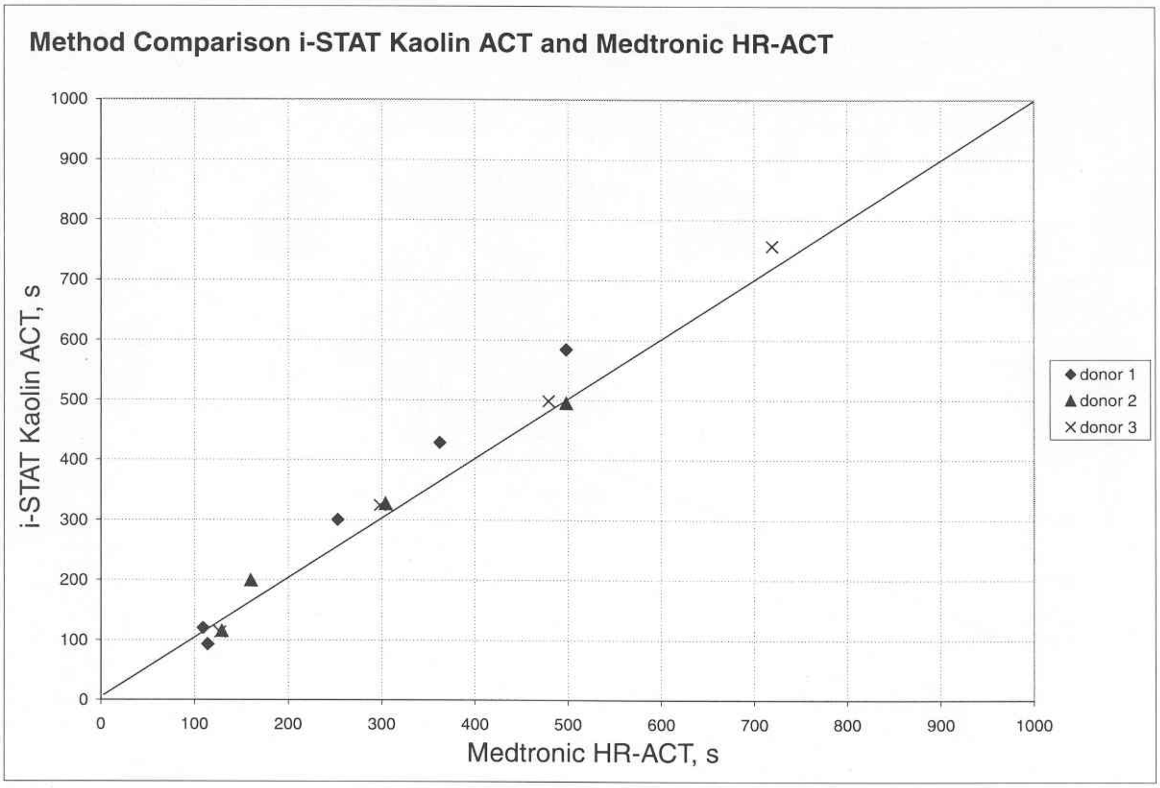

Heparin Linearity, Donor 1


Heparin Linearity, Donor 2



The following two graphs indicate the response of the same three donors with respect to the ACT result on the Medtronic HR-ACT and the Hemochron Kaolin FTK-ACT.





Test Limitations

The i-STAT ^{Kaolin}ACT test is to be used with fresh venous or arterial whole blood samples. The presence of exogenously added heparin, citrate, oxalate, or EDTA will interfere with test results. Poor technique in sample collection may also compromise the results. Samples drawn from insufficiently flushed catheters or from traumatic venipunctures may be contaminated with interfering substances. Samples should be collected into plastic syringes or tubes. Collection into glass may prematurely activate coagulation resulting in accelerated clotting times.

The analyzer should remain on a level surface with the display facing up during testing. If the analyzer is not level, the ACT result may be affected by more than 10%.

Hemodilution may affect test results.

Platelet dysfunction, factor deficiencies, dysprothrombinemias, pharmacological compounds, and other coagulopathies may affect the results of this test.

The i-STAT ACT test is not affected by fibrinogen concentration in the range from 100 - 500 mg/dL, or sample temperature from 15 - 37°C.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 25 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On each day the analyzers are in use, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperature was satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT ACT Controls using any verified Analyzer. Instructions for the use of these controls are found in the i-STAT System Manual.

For additional information on Quality Control of the i-STAT System, refer to the Quality Control section in the i-STAT System Manual.

Specimen Collection and Preparation

The i-STAT $^{\text{Kaolin}}$ACT test can be performed using venous or arterial samples.

Venipunctures and Arterial Punctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device cannot contain clot activators or serum separators.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is required, a fresh sample must be obtained.

Note: Some experts recommend drawing and discarding a sample of at least 1 mL prior to drawing sample for coagulation testing.[4]

In-dwelling line

- Fluid drip through the line must be discontinued.
- Withdraw 2 mL of blood into a syringe and discard it.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

Extracorporeal line

- Flush the extracorporeal blood access line by withdrawing 5 mL of blood into a syringe and discard the syringe.
- Withdraw the sample for testing into a fresh **plastic** syringe.
- The collection syringe **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The sample should be immediately dispensed into the sample well of a cartridge.
- If a second measurement is needed, draw a fresh sample.

References

1. Hattersly, P. Activated coagulation time of whole blood. Journal of the American Medical Association 136:436-440, 1966.

2. CLSI. *Method Comparison and Bias Estimation Using Patient Samples*; Approved Guideline. CLSI document EP9-A (ISBN 1-56238-283-7). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1995.

3. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

4. Corriveau, Donna: Fritsma, George (ed.): Hemostasis and Thrombosis in the Clinical Laboratory. Ed, J.B. Lippinncott Company, Philadelphia, 1988, pp 70-71.

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PROTHROMBIN TIME / (PT/INR)

The i-STAT® PT/INR test is a whole blood determination of the prothrombin time used for monitoring oral anticoagulant (warfarin) therapy. The test determines the time required for complete activation of the extrinsic pathway of the coagulation cascade when initiated (activated) with a thromboplastin.

In a prothrombin time test, coagulation is initiated by mixing the sample with tissue thromboplastin. In traditional prothrombin time tests, complete activation is indicated when activated thrombin converts fibrinogen to fibrin and extensive or localized clots are detected mechanically or optically. The i-STAT PT/INR test is similar except that the endpoint is indicated by the conversion of a thrombin substrate other than fibrinogen. An electrochemical sensor is used to detect this conversion.

The added thrombin substrate is H-D-phenylalanyl-pipecolyl-arginine-p-amino-p methoxydiphenylamine, which has the structure:

Phenylalanine - Pipecolic acid - Arginine -- NH - C_6H_4 - NH - C_6H_4 - OCH_3

Thrombin cleaves the amide bond at the carboxy terminus of the arginine residue (denoted by the two dashes) because the bond structurally resembles the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electrochemically inert tripeptide Phenylalanyl - Pipecolyl - Arginine and the electroactive compound NH_3^+ - C_6H_4 - NH - C_6H_4 - OCH_3. A formation of the electroactive compound is detected amperometrically and the time of detection is measured.

The PT/INR test result is reported as an International Normalized Ratio (INR) and, optionally, in seconds. The INR is the recommended method of result reporting for monitoring of oral anticoagulant therapy[1]. A Mean Normal i-STAT prothrombin time (sec) and an ISI are determined following the WHO recommendations at a CAP-accredited facility. INR results are calculated using the following equation:

$$\text{INR} = \left[\frac{\text{Patient i-STAT prothrombin time (sec)}}{\text{Mean Normal i-STAT prothrombin time (sec)}}\right]^{\text{ISI}}$$

The optionally displayed units of seconds reflect traditional plasma PT times. The reported time is derived from the PT/INR result and the equation below using an ISI of 1.05 and a typical Mean Normal Plasma PT time of 12.0 seconds.

$$\text{INR} = \left[\frac{\text{Patient Plasma prothrombin time (sec)}}{\text{Mean Normal Plasma prothrombin time (sec)}}\right]^{\text{ISI}}$$

If results appear inconsistent with the clinical assessment, the patient sample should be recollected and retested using another cartridge.

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Rev. Date: 02/12/07

Art: 715236-00G

Intended Use

The i-STAT PT/INR is an *in vitro* diagnostic test intended for quantitative prothrombin time testing for the monitoring of oral anticoagulation therapy using fresh capillary or venous whole blood samples. The i-STAT PT/INR test is not intended for evaluating individual factor deficiencies. The PT/INR is to be used with the i-STAT Portable Clinical Analyzer and i-STAT 1 Analyzer, but will not run on the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM). As part of the i-STAT System, the PT/INR test is to be used by trained and certified health care professionals in accordance with a facility's policies and procedures.

Contents

Each i-STAT PT/INR cartridge provides a sample collection chamber, sensors to detect the coagulation endpoint and dry reagents necessary to initiate and allow coagulation. Inert matrix components and reagents are coated on a section of the sensor channel and include the following reactive ingredients:

Reactive Ingredient	Biological Source
Recombinant Tissue Thromboplastin	Human
Heparinase I	*Flavobacterium heparinum*
Thrombin Substrate	N/A

Metrological Traceability

The i-STAT System test for Prothrombin Time (PT/INR) measures the International Normalized Ratio (dimensionless) expressing the relative time interval required for complete activation, by thromboplastin, of the coagulation cascade in capillary or venous whole blood for *in vitro* monitoring of oral anticoagulant (warfarin) therapy. PT/INR values assigned to i-STAT's controls are traceable to the World Health Organization (WHO) international reference measurement procedures and the WHO human recombinant thromboplastin International Reference Preparation[2]. i-STAT System controls are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units	Verified Clinical Range
Prothrombin Time/ (PT/INR)	INR	0.9 - 6.0*

*The performance characteristics of the i-STAT PT/INR measurement have not been established at INRs above 6.0.

Performance Characteristics

The typical performance data summarized below were collected in healthcare facilities by healthcare professionals trained in the use of the i-STAT System and comparative methods.

Imprecision

Typical imprecision data for venous whole blood samples are presented in the table below for sample duplicates collected at two clinical sites. Typical imprecision data for capillary whole blood samples are presented for sample duplicates collected at one clinical site using a single capillary stick.

Statistic	Site 1 (venous)	Site 2 (venous)	Site 3 (capillary)
n	181	102	33
Mean (INR)	2.6	2.4	2.5
%CV	4.7%	4.0%	4.6%

Typical imprecision data for lyophilized plasma material are presented below for studies performed at an Abbott Point of Care Inc. facility and during clinical trials.

Plasma Control	Mean	SD	%CV
Level 1	1.1 (INR)	0.05	4.5%
Level 2	2.5 (INR)	0.17	6.9%

Reference Interval

In a study to determine a reference interval for PT/INR, venous samples from healthy volunteers were collected in plastic tubes, and whole blood was analyzed with one lot of cartridges on the i-STAT System. Capillary samples were obtained from the same volunteers using Softclick Pro (setting of 3) and analyzed on the same cartridge lot. Reference intervals for INR in venous and capillary samples were determined according to the CLSI Guideline C28-A2.[3] The data are summarized in the table below:

Statistic	Venous whole blood	Capillary whole blood
n	120	119
Mean (INR)	1.0	1.0
SD	0.1	0.1
Reference Range (INR)	0.8 - 1.2	0.8 - 1.2

Due to the many variables that may affect PT/INR results, each laboratory should establish its own reference interval.

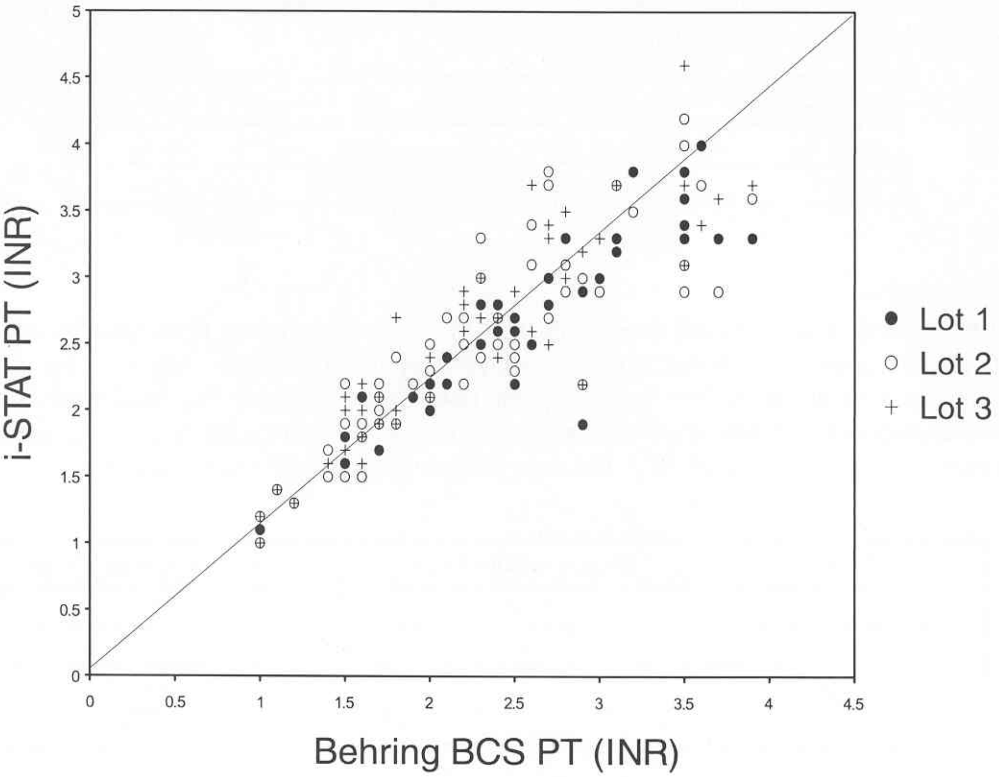
Method Comparison

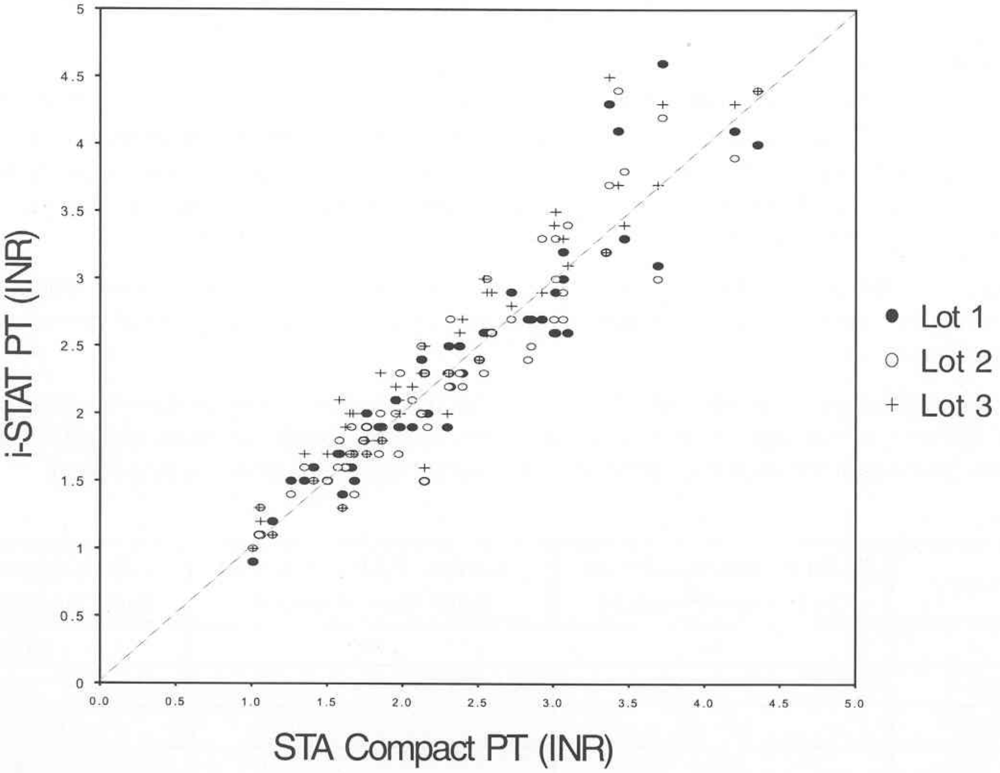
Method comparison data were collected at three clinical sites using a protocol in accordance with the CLSI Guideline EP9-A.[4] Venous samples from outpatients undergoing routine oral anticoagulation therapy were collected in plastic tubes and analyzed in duplicate on 3 lots of cartridges on the i-STAT System; plasma from tubes containing a citrate anticoagulant were analyzed in duplicate on the comparative instruments using Dade® Innovin® reagent.

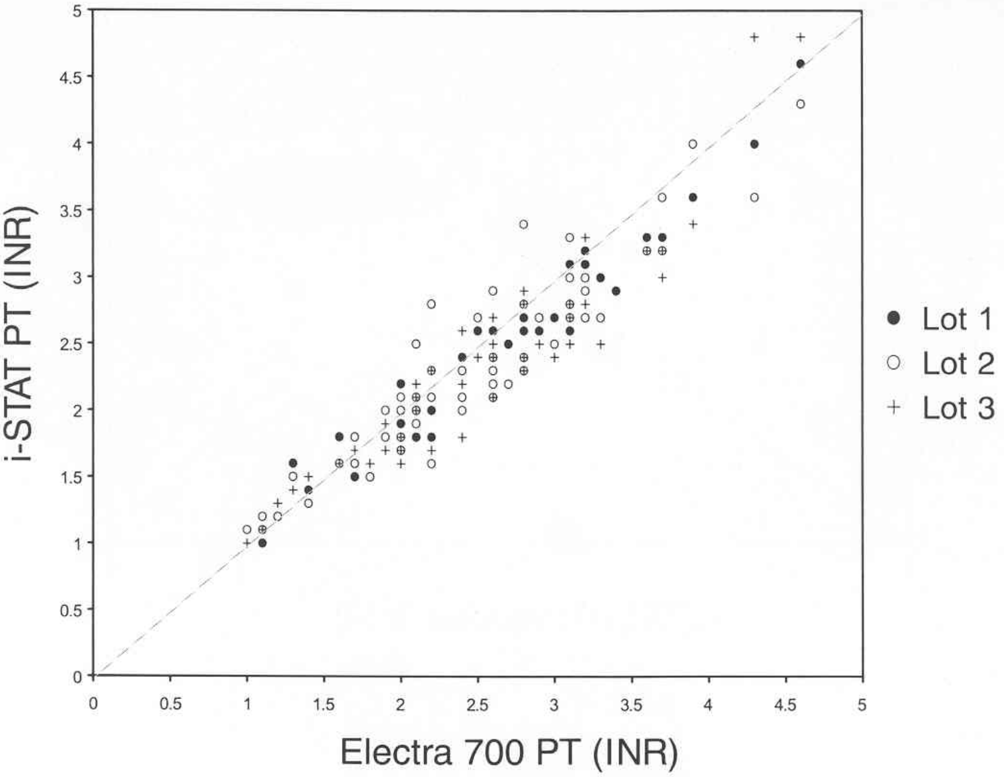
Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table below, *n* is the number of specimens in the data set, *Sy.x* is the standard error of the estimate, and *r* is the correlation coefficient.

Method comparisons will vary from site to site due to differences in the sample handling, reagent and instrument systems in use, and other site-specific variables. A correlation study should be performed to establish the differences between the i-STAT PT/INR measurement and other methods used.

Statistic	i-STAT vs. Behring BCS® and Dade® Innovin® reagent	i-STAT vs. STA Compact® and Dade® Innovin® reagent	i-STAT vs. Electra® 700 and Dade® Innovin® reagent
n	183	180	177
Mean (INR)	2.3	2.3	2.5
Range (INR)	1.0 – 3.9	1.0 – 4.3	1.0 – 4.6
Sx (INR)	0.729	0.777	0.779
Slope	0.922	1.013	0.914
Intercept (INR)	0.402	0.012	0.054
r	0.898	0.943	0.948
Sy.x	0.322	0.272	0.191

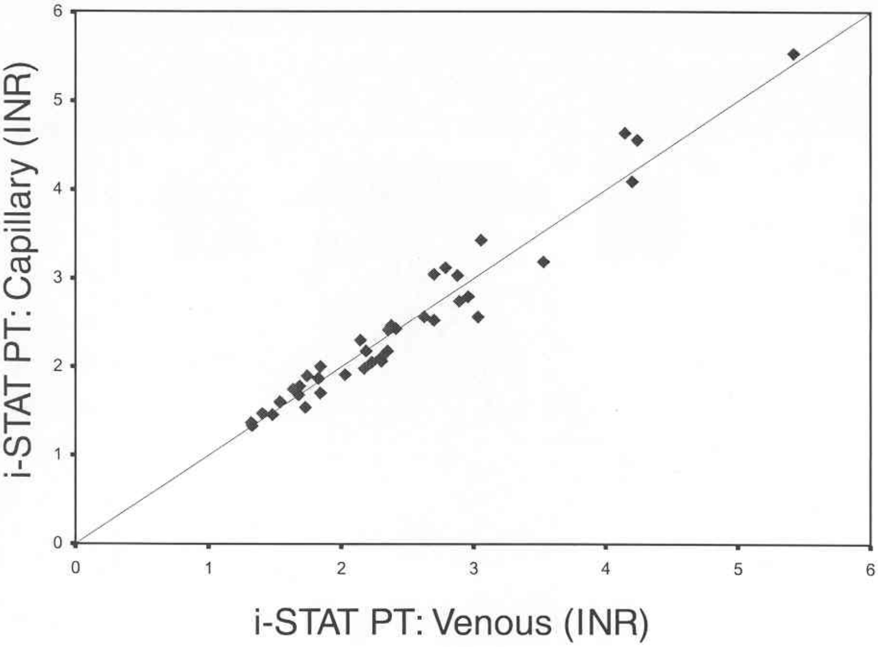

i-STAT PT (INR)
Behring BCS PT (INR)
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
5
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
● Lot 1
○ Lot 2
+ Lot 3


i-STAT PT (INR)
STA Compact PT (INR)
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
5
0.0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
● Lot 1
○ Lot 2
+ Lot 3



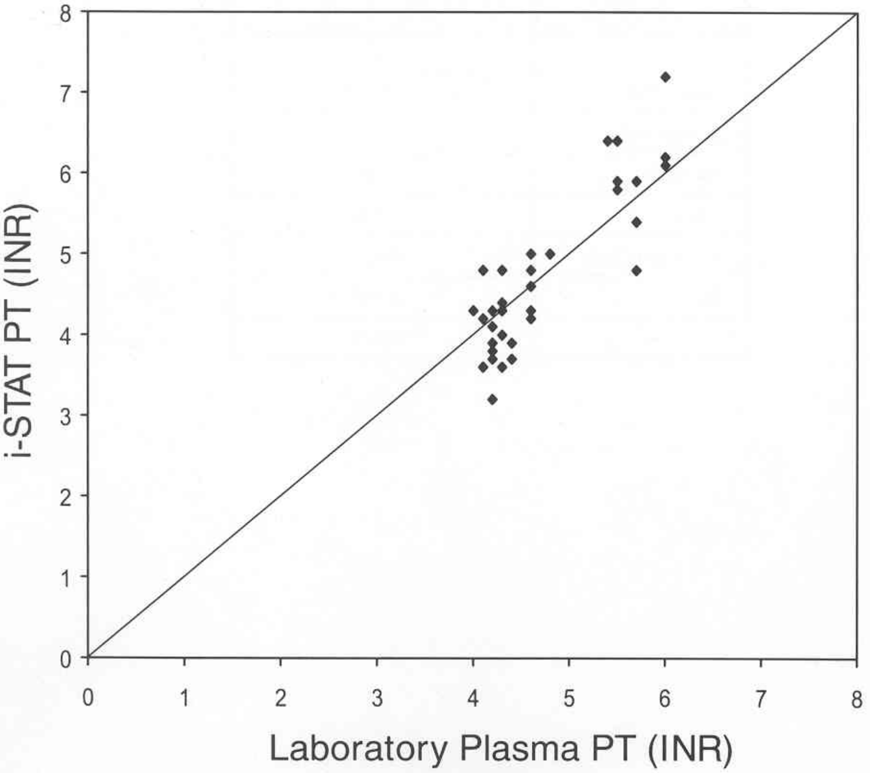
Data is presented below from one clinical site comparing data from capillary samples to data from venous samples analyzed on the i-STAT System.

Statistic	Capillary vs. Venous
n	39
Mean (INR)	2.4
Range (INR)	1.3 – 5.4
Sx (INR)	0.960
Slope	1.049
Intercept (INR)	-0.098
Sy.x	0.128
r	0.978



Performance Above the Therapeutic Range

Data are presented from multiple sites to demonstrate the performance at PT/INR levels above the therapeutic range (greater than an INR of 4.0 on the comparative instrument). Results from these sites are presented in the correlation graph below. The comparative method at all sites used a high-sensitivity (ISI approximately 1.0) recombinant (Dade® Innovin®) reagent.



Factors Affecting Results

- The presence of exogenously added heparin, citrate, oxalate, or EDTA from blood collection devices will interfere with test results.
- Poor technique in sample collection may compromise the results. (See Specimen Collection and Preparation below.)
- Glass syringes or tubes may prematurely activate coagulation, resulting in accelerated clotting times and lower INRs. Venous samples must be collected into plastic syringes or tubes.
- PT/INR results may be affected by commonly administered drugs.

Limitations of the i-STAT PT/INR Test

- The analyzer must remain on a level, vibration free surface with the display facing up during testing.
- The i-STAT PT/INR test is not affected by fibrinogen concentrations between 70 and 541 mg/dL.
- The i-STAT PT/INR test is not affected by heparin concentrations up to 1.0 U/mL.
- Hematocrits in the range of 24 – 54% PCV have been demonstrated not to affect results.
- Cubicin® (daptomycin for injection) has been found to cause a concentration-dependent false prolongation of prothrombin time (PT) and elevation of INR when using the i-STAT PT/INR test. It is recommended that for patients being treated with this antibiotic, an alternate method be used to evaluate PT/INR.

Storage Instructions

Cartridges in sealed pouches are stable through the expiration date when stored refrigerated at 2 to 8°C and for two weeks at room temperature (18 - 30°C).

Upon removal from refrigeration, a box of 24 cartridges requires one hour equilibration at room temperature before use. Individual cartridges require five minutes equilibration. A cartridge should be used immediately after it is removed from the pouch.

Quality Control

On a daily basis, the performance of all analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT PT/INR Controls using any verified analyzer. These controls should also be used to verify cartridge performance when storage conditions are in question. Instructions for the use of these controls is available with the i-STAT System Manual.

For additional information on Quality Control of the i-STAT System, refer to the "Quality Control" section in the i-STAT and i-STAT 1 System Manuals.

Specimen Collection and Preparation

Caution: The i-STAT PT/INR cartridge is designed to accept a sample between 20 and 45 microliters. A single drop of blood from either a finger puncture or as formed at the tip of a syringe will typically be within this range. If a larger volume is delivered to the sample well, use caution when closing the cartridge as excess blood may be expelled from the cartridge.

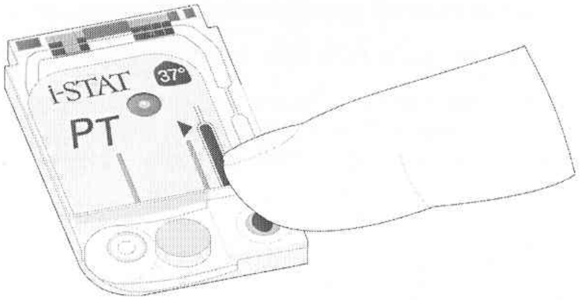
The i-STAT PT/INR test can be performed using capillary or venous samples.

Skin Punctures

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
4. Prick the bottom side of the fingertip with the lancet device.

5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. *Avoid strong repetitive pressure ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.*
6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7. Apply sample until it reaches the fill mark indicated on the cartridge.
8. Fold the sample closure over the sample well.
9. Press the rounded end of the closure until it snaps into place.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat vibration-free surface for testing.



Venipunctures

- Collection technique resulting in good blood flow must be used.
- The sample for testing should be drawn into a **plastic collection device** (either a plastic syringe or plastic evacuated tube).
- The collection device **cannot contain anticoagulants** such as heparin, EDTA, oxalate, or citrate.
- The collection device **cannot contain clot activators or serum separators.**
- The sample should be immediately dispensed into the sample well of a cartridge. A drop of blood should be touched against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
- If a second measurement is required, a fresh sample should be obtained.

Note: Some experts recommend drawing and discarding a (venous) sample of at least 1.0 mL prior to drawing sample for coagulation testing.[6]

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CARDIAC TROPONIN I / (cTnI)

Intended Use

The i-STAT cTnI test is an *in vitro* diagnostic test for the quantitative measurement of cardiac troponin I (cTnI) in whole blood or plasma samples. Cardiac troponin I measurements can be used as an aid in the diagnosis and treatment of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

The cartridge is to be used with the i-STAT®1 Analyzer bearing the i immuno symbol, but not with the i-STAT® Portable Clinical Analyzer or the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM). As part of the i-STAT System, the cTnI test is to be used by trained health care professionals in accordance with a facility's policies and procedures.

Method Explanation

The i-STAT cTnI test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

Contents

Each i-STAT cTnI cartridge provides a sample inlet, sensors to detect the cTnI as described above, and all the necessary reagents needed to perform the test. The cartridge contains a buffer and preservatives. A list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Antibody/Alkaline Phosphatase Conjugate	Caprine IgG: Bovine Intestine
IgG	Caprine IgG: Murine IgG
Sodium Aminophenyl Phosphate	N/A
Heparin	Porcine Intestine

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Metrological Traceability

The i-STAT System test for cardiac troponin-I (cTnI) measures cardiac troponin-I amount-of-substance concentration in plasma or the plasma fraction of whole blood (dimension ng mL^{-1}) for *in vitro* diagnostic use. Cardiac troponin-I values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from human cardiac troponin-ITC complex (Hy-Test Ltd., Turku, Finland, catalogue #8T62). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Reportable Range

The i-STAT cTnI test will report 0.00 to 50.00 ng/mL (µg/L). Samples above the reportable range will yield ">50.00 ng/mL" on the analyzer display screen. However, the performance characteristics of the i-STAT cTnI measurement have not been established for cTnI values above 35.00 ng/mL (µg/L).

Reference Range

Whole blood and plasma samples from 162 apparently healthy donors were assayed in duplicate using three different lots of i-STAT cTnI cartridges. The 0 to 97.5% range of results spanned 0.00 ng/mL (µg/L) to 0.03 ng/mL (µg/L). The 0 to 99% range of results spanned 0.00 ng/mL (µg/L) to 0.08 ng/mL (µg/L).

Note: Each facility should establish its own reference range using the i-STAT cTnI assay.

Clinical Significance

Biochemical cardiac markers, including cTnI, are useful for both the diagnosis of myocardial infarction and the risk stratification that can help guide the choice of therapeutic options.

For optimal diagnostic usefulness, a cardiac marker should be specific for cardiac tissue, should be rapidly released into the bloodstream with a direct proportional relationship between the extent of myocardial injury and the measured level of the marker, and should persist in blood for a sufficient length of time to provide a convenient diagnostic time window.[1] The cardiac-specific troponins, troponin I (cTnI) and troponin T (cTnT) are considered the biochemical markers of choice in the evaluation of acute coronary syndromes (ACS) including ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina. Since cTnI is not generally detected in the blood of healthy persons, any level of cTnI above the upper limit of the reference range defined in a normal healthy population should be considered indicative of myocardial necrosis.[1] Each institution should establish its own reference range for its patient population, and this range should be used to determine an appropriate limit indicative of acute myocardial infarction.

Elevated levels of cardiac-specific troponins convey prognostic information beyond that supplied by the patient's clinical signs and symptoms, the ECG at presentation, and the pre-discharge exercise test.[1] Antman, *et al.*, reported that patients with elevated levels of cTnI had a statistically significant increase in mortality ($p<0.001$) when compared to patients without cTnI elevations.[2] Also, the study revealed that there is a quantitative relationship between the cTnI level measured and the risk of death in ACS patients ($p<0.001$). Other studies have shown increases in other non-fatal cardiac events such as non-fatal MI, congestive heart failure, and urgent revascularization with increasing levels of cTnI.[3,4,5]

In addition, the ability of cTnI to be measured at the low-end of the concentration range allows therapeutic intervention to be considered at any elevation above the normal range. Patients that present with no ST-elevation on their ECG but who have even slight elevation in cTnI or cTnT may receive a greater treatment benefit from certain drugs such as GP IIb/IIIa inhibitors or low molecular weight heparins.[6,7,8]

Other conditions like blunt trauma or myocarditis that are not secondary to ischemic coronary artery disease can also lead to myocardial injury and have the potential to cause elevations in the blood concentrations of cTnI. These conditions should be considered when interpreting results, and the cTnI level should be used in conjunction with clinical symptoms, signs, and ECG changes.[1]

Performance Characteristics

Precision data were collected in multiple sites as follows: Duplicates of each control were tested daily for a period of 20 days, resulting in a total of 40 replicates. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A.[9] Venous blood samples were collected in heparinized evacuated tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on the comparative method within 1 hour of collection.

Deming regression analysis[10] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7.[11]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid".[9] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (ng/mL)

Aqueous Control	Mean	SD	%CV
Level 1	0.53	0.04	7.8
Level 2	2.17	0.18	8.5
Level 3	31.82	2.42	7.6

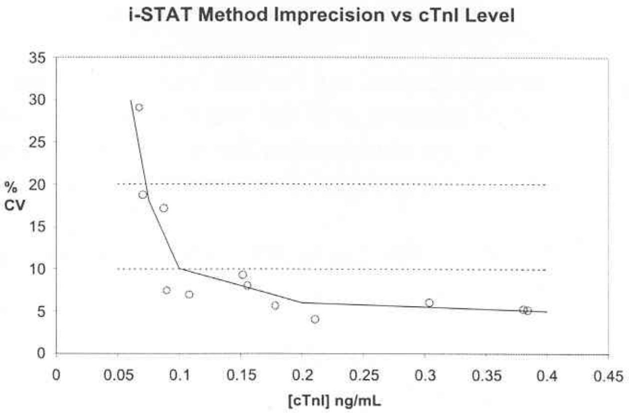
Method Comparison (ng/mL)

	Dade Behring Stratus® CS
n	189
Sxx	0.28
Syy	0.31
Slope	0.883
Int't	0.029
Sy.x	1.40
Xmin	0.00
Xmax	46.27
r	0.975

Analytical and Functional Sensitivities

The analytical sensitivity of the cTnI method is 0.02 ng/mL, which is the lowest cTnI level that can be distinguished from zero. The analytical sensitivity is defined as the concentration at two standard deviations from a sample at 0.00 ng/mL.

Another characteristic of an analytical measurement is the functional sensitivity, which is defined as the cTnI level at which the test method displays a particular percent coefficient of variation (%CV). Estimates of the 20% and 10% functional sensitivity for the cTnI method were determined from whole blood measurements. The 20% and 10% functional sensitivities for the cTnI method are 0.07 ng/mL and 0.10 ng/mL, respectively (see graph below).



Analytical Specificity

The cTnI method is specific for cardiac troponin I. The following muscle proteins were tested and found to have an insignificant effect on the measured cTnI.

Crossreactant	Concentration	Percent Crossreactivity
Troponin C (cardiac)	1000 ng/mL	<0.002%
Troponin T (cardiac)	1000 ng/mL	0.65%
Troponin I (skeletal)	1000 ng/mL	<0.002%
Troponin T (skeletal)	1000 ng/mL	<0.002%

Recovery

The dilution linearity of the i-STAT cTnI test was investigated using heparinized whole blood and plasma samples derived from 3 separate donors. For each donor, the original cTnI negative sample and a cTnI spiked sample were prepared. This process yielded three cTnI positive whole blood samples that were then assayed in duplicate for each of three separate i-STAT cTnI cartridge lots. These whole blood samples were then diluted using an equal mass of the original unspiked whole blood and assayed in duplicate. From this whole blood data, the cTnI recovery was calculated.

The plasma derived from these three donors was combined in equal masses and all pairwise combinations. These combinations were then assayed in duplicate for each of three separate i-STAT cTnI cartridge lots. The cTnI recovery for each pair was calculated using the average of the 6 results. The % recoveries are listed in the Tables below.

Whole blood

Sample	Concentration	Diluted Concentration	% Recovery
A	2.05	1.04	101%
B	6.31	3.14	100%
C	27.04	14.05	104%

Plasma

Sample	Concentration	Diluted Concentration	% Recovery
A	2.41	-----	-----
B	7.50	-----	-----
C	29.35	-----	-----
A+B	-----	4.69	95%
B+C	-----	18.90	103%
A+C	-----	16.89	106%

Test Limitations

Partially clotted samples can result in elevated cTnI readings above the reference range, as well as quality check code errors. To prevent this from occurring, upon drawing the whole blood sample into a heparized collection tube, the sample should be inverted gently at least 10 times to insure even dissolution of the heparin anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of cTnI, increased assay backgrounds, and/or quality check codes.

Hematocrits in the range of 0-65 % PCV have been demonstrated not to affect results. Samples with hematocrit levels above this range have demonstrated increases in the test imprecision and quality check codes.

The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.

Storage Instructions

Please see the “Shelf Life” and “Preparation for Use” sections on page 1 of the Cartridge and Test Information section of the i-STAT 1 System Manual.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT Cardiac Marker Controls using any verified Analyzer. These controls should also be used to verify cartridge performance when storage conditions are in question.

For additional information on Quality Control of the i-STAT System, refer to the “Quality Control” section of the i-STAT 1 System Manual.

Specimen Collection and Preparation.

i-STAT cTnI cartridges require the use of either:

1. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or
2. non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives. The cartridge contains sufficient reagent to heparinize the freshly drawn sample.

   The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased cTnI readings. **Capillary tubes and direct skin punctures (e.g. fingersticks) should not be used with the cTnI cartridge**.

The i-STAT cTnI cartridge requires a minimum sample volume of 17 µL of sample to fill. Excess amounts beyond this requirement will not impair the results. However, excess blood or plasma will be present at the inlet of the cartridge and caution should be observed in handling the cartridge to minimize biohazard exposure.

Samples should not be used unless the blood collection tube is filled at least half full.

For best results, samples must be mixed well before transfer to a cartridge. Immediately after filling the cartridge, the sample port should be closed and the cartridge inserted into the analyzer.

Interference Testing

The following substances were found to have no significant effect (less than 10%) on the cTnI method, when added to a plasma pool containing approximately 2 ng/mL of cardiac troponin I, at the concentrations indicated:

Compound	Test Level (µmol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ascorbic Acid	227
Acetyl Salicylic Acid	3330
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin*	36 U/mL
Ibuprofen	2425
Isosorbide dinitrate	0.636

Compound	Test Level (µmol/L unless otherwise indicated)
Methyldopa	71
Nicotine	6.2
Nifedipine	1.156
Phenytoin	198
Propanolol	7.71
Salicylic Acid	4340
Theophylline	222
Verapamil	4.4
Warfarin	64.9

*Heparin at 90U/mL was found to decrease the cTnI level by approximately 20%.

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CREATINE KINASE MB/ (CK-MB)

Intended Use

The i-STAT CK-MB test is an *in vitro* diagnostic test for the quantitative measurement of creatine kinase MB mass in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis of myocardial infarction (MI), re-infarction, and the sizing of infarction. CK-MB measurements can also be used in monitoring reperfusion during thrombolytic therapy and perioperative myocardial infarction (poMI) after cardiac surgery.

The cartridge is to be used with the i-STAT 1 Analyzer bearing the i immuno symbol, but not with the i-STAT Portable Clinical Analyzer or the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM). As part of the i-STAT System, the CK-MB test is to be used by trained health care professionals in accordance with a facility's policies and procedures

Method Explanation

The i-STAT CK-MB test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for an epitope unique to the CK-MB subunit, that therefore do not bind CK-MM or CK-BB, are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to an epitope on the B subunit of creatine kinase. The specificity of the conjugate antibody to the B subunit allows this conjugate to recognize CK-MB and CK-BB, but not CK-MM. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The CK-MB within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately three minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of CK-MB within the sample.

Contents

Each i-STAT CK-MB cartridge provides a sample inlet, sensors to detect the CK-MB as described above, and all the necessary reagents needed to perform the test. The cartridge contains a buffer and preservatives. A list of reactive ingredients is indicated below:

Reactive Ingredient	Reactive Ingredient
Antibody/Alkaline Phosphate Conjugate	Murine IgG: Bovine Intestine
IgG	Caprine IgG: Murine IgG
Sodium Aminophenyl Phosphate	N/A
Heparin	Porcine Intestine

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Metrological Traceability

The i-STAT System test for creatine kinase-MB (CK-MB) measures creatine kinase-MB amount-of-substance concentration mass in plasma or the plasma fraction of venous whole blood (dimension ng/mL^{-1}) for *in vitro* diagnostic use. Creatine kinase-MB values assigned to i-STAT System controls are traceable to the American Association of Clinical Chemists (AACC recombinant human CK-MB from Seradyn Inc.) calibrator for the standardization of creatine kinase mass assays. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Reportable Range

The i-STAT CK-MB test will report 0.0 to 150.0 ng/mL (µg/L). Samples above the reportable range will yield ">150.0 ng/mL" on the analyzer display screen.

Reference Range

Whole blood and plasma samples from 161 apparently healthy donors were assayed in duplicate using 3 different lots of i-STAT CK-MB cartridges. The 0 to 95% range of results spanned 0.0 ng/mL (µg/L) to 3.5 ng/mL (µg/L).

Note: Each facility should establish its own reference range using the i-STAT CK-MB assay

Clinical Significance

CK-MB mass has been reported to be useful for the diagnosis of myocardial infarction, re-infarction, and the sizing of infarction.

For optimal diagnostic usefulness, a cardiac marker should be specific for cardiac tissue, should be rapidly released into the bloodstream with a direct proportional relationship between the extent of myocardial injury and the measured level of the marker, and should persist in blood for a sufficient length of time to provide a convenient diagnostic time window.[1]

Creatine kinase (CK) is a dimeric enzyme found primarily in brain and muscle tissue. There are 3 isoforms of creatine kinase: BB, MM, and MB. BB is found primarily in the brain. Skeletal muscles primarily contain the MM isoform, with traces of MB (estimates of 1-4% of CK activity). Cardiac muscles also contain primarily the MM isoform, but higher amounts of MB, typically around 20% of CK activity.[2] Serum from healthy individuals typically contains the MM isoform and a small amount of the MB isoform.. CK-MB can be released into the bloodstream by a number of actions, including skeletal muscle injury and myocardial damage.

The rise in CK-MB in the bloodstream occurs between 4-6 hours following a myocardial infarction (MI). The concentration peaks after approximately 24 hours and returns to baseline after 36-72 hours. As the level of CK-MB is not cardiac specific, the results of a single test are not indicative of a myocardial infarction (MI). Typically an MI is diagnosed based on the pattern of CK-MB analyses taken at 3 hour intervals for a 6 to 9 hour period or at 6 to 8 hour intervals for a 24 hour period.

Although the cardiac-specific troponins, troponin I (cTnI) and troponin T (cTnT) are now considered the biochemical markers of choice in the evaluation of acute coronary syndromes (ACS) including ST-elevation myocardial infarction, non-ST-elevation myocardial infarction, and unstable angina, CK-MB can also be used as a secondary marker to aid in the diagnosis of myocardial infarction and measuring the degree of myocardial necrosis. Since low levels of CK-MB can be detected in the blood of healthy persons, any CK-MB value above the 95th percentile may be indicative of some degree of myocardial necrosis.[1] Each institution should establish its own reference range for its patient population, and this range should be used to determine an appropriate limit indicative of acute myocardial infarction (AMI).

The European Society of Cardiology / American College of Cardiology consensus document notes that in the clinical setting of a reinfarction, CK-MB may be more useful for monitoring for MI than cardiac troponin I (cTnI) or cardiac troponin T (cTnT) because CK-MB remains increased for only 2-4 days following an MI, in contrast to up to 5 days for cTnI or 10 days for cTnT.[3,4,5,6,7] Clinical studies have also demonstrated a close relationship between the extent of injury to the myocardium (infarct size) following MI and increased serum CK-MB mass concentrations.[8] Similarly, significant correlations have been observed between CK-MB estimated infarct sizing and left ventricular echocardiography.[8]

Other conditions involving skeletal muscle damage like accidents, blunt trauma, severe burns, and extreme exercise or myopathic disorders such as myocarditis that are not secondary to ischemic coronary artery disease can also lead to skeletal muscle or myocardial injury and have the potential to cause elevations in the blood concentrations of CK-MB. These conditions should be considered when interpreting results, and the CK-MB level should be used in conjunction with clinical symptoms, signs, patient history, and ECG changes.[1,9]

Performance Characteristics

Precision data were collected in multiple sites as follows: Duplicates of each control were tested daily for a period of 20 days for each of three lots of cartridges, resulting in a total of 120 replicates. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A2.[10] Venous blood samples were collected in heparinized evacuated tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on the i-STAT System and on the comparative method within 1 hour of collection.

Deming regression analysis[11] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

Interference studies were based on CLSI guideline EP7-A.[12]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid",[10] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (ng/mL)

Plasma Control	Mean	SD	%CV
Level 1	5.9	0.7	11.9
Level 2	25.8	2.7	10.4
Level 3	90.1	9.0	10.0

Method Comparison (ng/mL)

	Abbott AxSYM
n	263
Sxx	1.84
Syy	2.66
Slope	1.01
Int't	-0.19
Sy.x	3.98
Xmin	0.04
Xmax	224
r	0.994

Analytical Sensitivities

The sensitivity of the CK-MB method is 0.6 ng/mL, which is the lowest CK-MB level that can be distinguished from zero. The analytical sensitivity is defined as two standard deviations associated with a zero calibrator. The analytical sensitivity was estimated using a control material with < 1 ng/mL CK-MB during a 20 day precision study in which three separate lots of CK-MB test cartridges were tested in duplicate using a pool of 6 i-STAT 1 analyzers for a total of 120 test results.

Analytical Specificity

The CK-MB method is specific for the creatine kinase MB isoenzyme. The following muscle proteins were tested and found to have an insignificant effect on the measured CK-MB.

Crossreactant	Concentration	Percent Crossreactivity
CK-MM (skeletal)	10000 ng/mL	Not Detectable
CK-BB (brain)	100 ng/mL	Not Detectable

Recovery

The dilution linearity of the i-STAT CK-MB test was investigated using heparinized whole blood and plasma samples derived from 3 separate donors. For each donor, the original CK-MB negative sample and a CK-MB spiked sample were prepared. This process yielded three CK-MB positive whole blood samples that were then assayed in duplicate for each of three separate i-STAT CK-MB cartridge lots. These whole blood samples were then diluted using an equal mass of the original unspiked whole blood and assayed in duplicate. From this whole blood data, the CK-MB recovery was calculated.

The plasma derived from these three donors was combined in equal masses and all pairwise combinations. These combinations were then assayed in duplicate for each of three separate i-STAT CK-MB cartridge lots. The CK-MB recovery for each pair was calculated using the average of the 6 results. The % recoveries are listed in the Tables below.

Whole Blood

Sample	Concentration *(ng/mL)*	Diluted Concentration *(ng/mL)*	% Recovery
A	73.24	40.73	108.7%
B	8.90	6.07	101.5%
C	47.74	26.91	109.3%

Plasma

Sample	Concentration *(ng/mL)*	Diluted Concentration *(ng/mL)*	% Recovery
A	73.24	—	—
B	8.90	—	—
C	47.74	—	—
A+B	—	42.17	108.9%
B+C	—	30.85	102.7%
A+C	—	63.95	105.7%

Test Limitations

Partially clotted samples can result in elevated CK-MB readings above the reference range, as well as quality check code errors. To prevent this from occurring, upon drawing the whole blood sample into a heparinized collection tube, the sample should be inverted gently at least 10 times to ensure even dissolution of the heparin anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of CK-MB, increased assay backgrounds, and/or quality check codes.

Hematocrits in the range of 0-70 % PCV have been demonstrated not to affect results. Samples with hematocrit levels above this range have demonstrated increases in the test imprecision and quality check codes.

The analyzer must remain on a flat surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.

Storage Instructions

Please see the "Shelf Life" and "Preparation for Use" sections on page 1 of the Cartridge and Test Information section of the i-STAT 1 System Manual.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of Cliniqa Cardiac Marker Controls for use on the i-STAT System using any verified i-STAT 1 Analyzer. These controls should also be used to verify cartridge performance when storage conditions are in question.

For additional information on Quality Control of the i-STAT System, refer to the "Quality Control" section of the i-STAT 1 System Manual.

Specimen Collection and Preparation

i-STAT CK-MB cartridges require the use of either:

1. heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin, or
2. non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives. The cartridge contains sufficient reagent to heparinize the freshly drawn sample.

The use of whole blood or plasma samples containing other anticoagulants such as EDTA, oxalate, and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased CK-MB readings. **Capillary tubes and direct skin punctures (e.g. fingersticks) should not be used with the CK-MB cartridge**.

The i-STAT CK-MB cartridge requires a minimum sample volume of 17 μL of sample to fill. Excess amounts beyond this requirement will not impair the results. However, excess blood or plasma will be present at the inlet of the cartridge and caution should be observed in handling the cartridge to minimize biohazard exposure.

When drawn into an evacuated tube containing heparin, samples should not be used unless the blood collection tube is filled at least half full.

For best results, samples must be mixed well before transfer to a cartridge. Immediately after filling the cartridge, the sample port should be closed and the cartridge inserted into the analyzer.

Interference Testing

When added to a plasma pool containing approximately 20 ng/mL of creatine kinase MB isoenzyme, the following substances were found to have no significant effect (less than 10%) on the CK-MB method at the concentrations indicated

Compound	Test Level (μmol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ampicillin	152
Ascorbic Acid	227
Acetyl Salicylic Acid	3330
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin	90 U/mL
Ibuprofen	2425
Isosorbide dinitrate	0.636

Compound	Test Level (µmol/L unless otherwise indicated)
Methyldopa	71
Nicotine	6.2
Nifedipine	1156
Phenytoin	198
Propanolol	7.71
Salicylic Acid	4.34
Theophylline	222
Verapamil	4.4
Warfarin	64.9

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B-TYPE NATRIURETIC PEPTIDE / (BNP)

Intended Use

The i-STAT BNP test is an in vitro diagnostic test for the quantitative measurement of B-type natriuretic peptide (BNP) in whole blood or plasma samples using EDTA as the anticoagulant. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure.

The cartridge is to be used with the i-STAT 1 Analyzer bearing the i Immuno symbol, but not with the i-STAT Portable Clinical Analyzer or the Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM). As part of the i-STAT System, the BNP test is to be used by trained health care professionals in accordance with a facility's policies and procedures.

Method Explanation

The i-STAT BNP test cartridge uses a two-site enzyme-linked immunosorbant assay (ELISA) method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample.

Contents

Each i-STAT BNP cartridge provides a sample inlet, sensors to detect the BNP as described above, and all the necessary reagents needed to perform the test. The cartridge contains a buffer and preservatives. A list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Antibody/Alkaline Phosphatase Conjugate	Murine IgG: Bovine Intestine
IgG	Caprine IgG: Murine IgG
Sodium Aminophenyl Phosphate	N/A
Heparin	Porcine Intestine

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Metrological Traceability

The i-STAT System test for B-type natriuretic peptide (BNP) measures BNP amount-of-substance concentration in plasma or the plasma fraction of EDTA anticoagulated whole blood (units of measure: pg/mL or ng/L) for in vitro diagnostic use. BNP values assigned to i-STAT's controls and calibration verification materials are traceable to i-STAT's working calibrator prepared from synthetic BNP (Peptide International, Louisville, KY, Cat# 4212v). i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc.

Reportable Range

The i-STAT BNP test will report 15 to 5000 pg/mL (ng/L). Samples below the reportable range will yield "<15 pg/mL" on the analyzer display screen. Samples above the reportable range will yield ">5000 pg/mL".

Reference Range

Whole blood and plasma samples from 165 apparently healthy donors were assayed. The upper 95% reference range was determined to be 50 pg/mL (ng/L).

Note: Each facility should establish its own reference range using the i-STAT BNP assay.

Clinical Significance

Congestive heart failure (CHF) is a complex clinical syndrome resulting in decreased cardiac output that is insufficient to meet the body's metabolic needs.[1] It may result from dysfunction of either ventricle in systole (contraction), diastole (relaxation) or both.[2] The most common underlying cause of CHF is coronary artery disease. Other causes include: hypertension, myocarditis, valvular heart disease and idiopathic (unknown).[3]

Common symptoms include: paroxysmal nocturnal dyspnea (PND), orthopnea, dyspnea on exertion (DOE), nocturnal cough and peripheral edema.[2] Clinical signs include elevated jugular venous pressure, rales on lung auscultation, the presence of a third heart sound and peripheral edema.2 Unfortunately, these signs and symptoms are variable, and when present, non-specific as other clinical entities such as chronic obstructive pulmonary disease can produce a similar clinical picture.[4]

B-type natriuretic peptide (BNP) is one of a family of structurally similar peptide neurohormones that also includes atrial natriuretic peptide (ANP) and C-type natriuretic peptide (CNP) whose function is to regulate blood pressure, electrolyte balances, and fluid volume. ANP is stored in granules within the atria and released rapidly in response to atrial stretch. In contrast, BNP is synthesized, stored, and released primarily by the ventricular myocardium in response to volume expansion and pressure overload.1 Pre-pro-BNP (134 amino acids) is synthesized in the cardiac myocytes and is processed to a pro-BNP (108 amino acids) precursor molecule. The pro-BNP is then subsequently cleaved into the physiologically active BNP (32 amino acids) and an N-terminal fragment referred to as N-Terminal pro-BNP (76 amino acids).[3]

Numerous clinical trials suggest the potential clinical usefulness of plasma BNP in:

1. the diagnosis of dyspnea and CHF[4,5,]
2. the detection of left ventricular systolic and diastolic dysfunction[6,7,]
3. the prognosis of patients with CHF and acute coronary syndromes[8,9,] and
4. therapy monitoring for CHF patients[10,11.]

Multiple studies establish the value of BNP for facilitating the diagnosis of CHF in patients presenting with dyspnea.[12] Davis, et al, measured levels of ANP and BNP in 52 patients presenting with acute dyspnea.[12,13] They found that admission plasma BNP concentrations more accurately reflected the final diagnosis than did ejection fraction (EF) levels or ANP plasma concentrations. Morrison, et al also showed that rapid testing of BNP could help differentiate pulmonary from cardiac etiologies of dyspnea.[4] Furthermore, the Task Force of the European Society of Cardiology for the Diagnosis and Treatment of Chronic HF has included the use of natriuretic peptide (e.g. BNP) testing along with electrocardiography and chest x-rays in their guidelines for the diagnosis or rule out of HF.[14]

The Breathing Not Properly study, a 1586 patient multinational prospective study, validated the clinical utility of rapid measurement of BNP, used in conjunction with other clinical information, for the diagnosis or exclusion of CHF in the emergency department15. BNP levels were much higher in patients with subsequent CHF than in those with non-cardiac dyspnea (675 pg/mL vs 110 pg/mL). A BNP cutoff value of 110 pg/mL had a sensitivity of 90% and a specificity of 76% for differentiating CHF from other causes of dyspnea, and a cutoff value of 50 pg/mL had a negative predicative value of 96%. There was a 43% indecision rate among physicians in the ED trying to make a diagnosis in patients with dyspnea. Had BNP levels been available to those physicians, the indecision rate would have been reduced to 11%. In multivariate analysis, BNP levels always contributed to the diagnosis, even after consideration of the history and physical exam.

BNP levels are also raised in patients with left ventricular dysfunction, and the values can be used to assess the severity of CHF, as they correlate with both New York Heart Association (NYHA) functional class and patient prognosis.[16]

Steg, et al indicated in 2005 that BNP measurement is consistently superior to a single echocardiographic determination of left ventricular EF in identifying patients with CHF, regardless of the threshold value.[16] Two-dimensional echocardiography was less sensitive than a single determination of BNP in diagnosing CHF. However, the two variables have marked additive diagnostic value and when combined have a much-improved accuracy compared to either method alone. This strongly suggests that, where applicable, they should be used together.[16]

Studies also indicate that BNP also has a burgeoning role in the prognostic assessment of patients with heart failure.[17] BNP is a powerful prognostic indicator for patients with CHF at all stages of the disease and seems to be a better predictor of survival than many traditional prognostic indicators, such as New York Heart Association class, serum creatinine values, and possibly left ventricular ejection fraction.[18] The relative risk of death increases by about 35% for each 100 pg/mL increase in BNP in patients with CHF.[18] Raised BNP values also predict the survival in patients not known to have CHF, with the risk doubled in patients with a BNP value >20 pg/mL.[18]

BNP has also been shown to predict morbidity and mortality in other cardiovascular conditions, such as acute coronary syndromes and acute myocardial infarction.[19] ACS patients with increased BNP levels have a higher rate of cardiac complications and higher mortality post myocardical infarction.

When a panel of neurohormones (including BNP and catecholemines) was measured one to four days after acute infarction, BNP was the only independent predictor of late ejection fraction (EF <40%) and was the most powerful predictor of death within four months after infarction.[20] In 2,525 AMI patients, the magnitude of BNP elevation correlated with mortality, heart failure, and recurrent infarction at both 30 days and 10 months.[8] A strategy of combining EF and BNP improved risk stratification beyond using either alone.[21]

EXPECTED VALUES

Non-heart Failure Population

Plasma samples from 890 individuals (465 females, 425 males) who had not been diagnosed with heart failure were tested with the AxSYM® BNP assay. This population included non-hospitalized patients with renal disease (not on dialysis), diabetes, hypertension and chronic obstructive pulmonary disease. BNP levels for the patients with renal disease, diabetes, hypertension and chronic obstructive pulmonary disease were not statistically different from the population of apparently healthy individuals. The data from this study are summarized in the following table.*

Non-Heart Failure Population - All (Age Group)

	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sample Size (N=)	890	205	146	171	248	120
Median (pg/mL)	21	17	9	24	23	31
Mean (pg/mL)	39	28	21	37	47	63
SD (pg/mL)	66	36	30	48	80	109
95th Percentile	135	85	87	119	160	254
Percentage < 100 pg/mL	91.5%	96.6%	95.2%	94.2%	87.1%	83.3%
Minimum (pg/mL)	0	0	0	0	0	0
Maximum (pg/mL)	907	263	142	380	907	837

Non-Heart Failure Population - Males (Age Group)

	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sample Size (N=)	425	107	71	94	115	38
Median (pg/mL)	14	12	1	17	21	37
Mean (pg/mL)	30	23	9	26	47	49
SD (pg/mL)	61	34	14	45	96	51
95th Percentile	104	73	40	80	150	121
Percentage < 100 pg/mL	94.8%	97.2%	100.0%	97.9%	88.7%	89.5%
Minimum (pg/mL)	0	0	0	0	0	0
Maximum (pg/mL)	907	200	57	380	907	254

Non-Heart Failure Population - Females (Age Group)						
	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sample Size (N=)	465	98	75	77	133	82
Median (pg/mL)	26	23	23	37	23	25
Mean (pg/mL)	46	34	34	51	46	69
SD (pg/mL)	70	37	36	48	63	126
95th Percentile	150	89	111	155	159	266
Percentage < 100 pg/mL	88.4%	95.9%	90.7%	89.6%	85.7%	80.5%
Minimum (pg/mL)	0	0	0	0	0	0
Maximum (pg/mL)	837	263	142	230	374	837

* Representative data, results in individual laboratories may vary from these data.

Due to demographic population differences, the reference range should be established at each laboratory.

Heart Failure Population

Plasma samples from 693 patients with diagnosed heart failure (231 females, 462 males) were tested with the AxSYM BNP assay. All patients in this population were categorized according to the functional classification system published by the New York Heart Association (NYHA).[22] This system divides heart failure patients into one of four categories of increasing disease progression (classes I to IV) based upon a subjective assessment of the patient's clinical signs and symptoms. The data from this study are summarized in the following table.*

Heart Failure Population - All					
		NYHA Functional Class			
	All	I	II	III	IV
Sample Size (N=)	693	124	319	190	60
Median (pg/mL)	298	133	266	335	1531
Mean (pg/mL)	578	320	432	656	1635
SD (pg/mL)	771	388	574	841	1097
5th Percentile	14	9	15	12	188
95th Percentile	2154	1257	1534	2516	>4000
Percentage ≥ 100 pg/mL	74.2%	58.1%	73.0%	79.0%	98.3%
Minimum (pg/mL)	0	3	0	0	14
Maximum (pg/mL)	>4000	1651	>4000	>4000	>4000

Heart Failure Population - Males

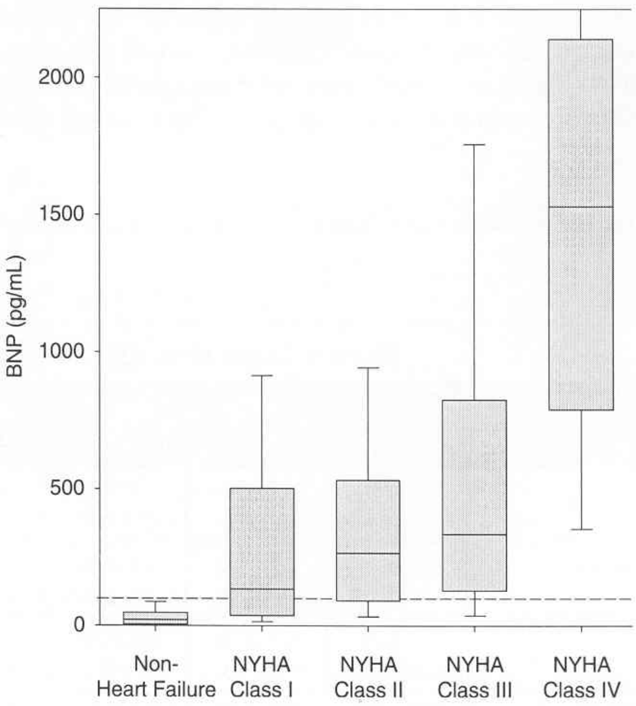
		NYHA Functional Class			
	All	**I**	**II**	**III**	**IV**
Sample Size (N=)	462	94	215	121	32
Median (pg/mL)	268	122	258	293	1645
Mean (pg/mL)	524	314	409	597	1646
SD (pg/mL)	719	390	539	821	1032
5th Percentile	12	9	14	22	265
95th Percentile	1976	1281	1356	2288	3654
Percentage ≥ 100 pg/mL	71.0%	56.4%	70.7%	76.0%	96.9%
Minimum (pg/mL)	0	3	0	0	14
Maximum (pg/mL)	>4000	1408	3782	>4000	>4000

Heart Failure Population - Females

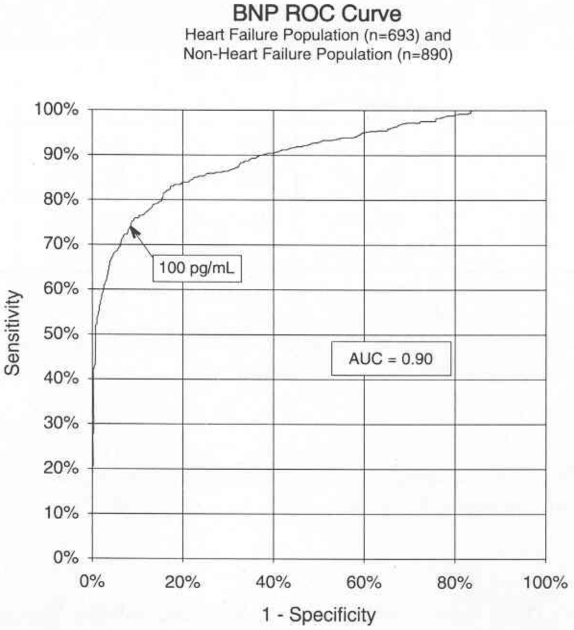
		NYHA Functional Class			
	All	**I**	**II**	**III**	**IV**
Sample Size (N=)	231	30	104	69	28
Median (pg/mL)	385	174	298	466	1408
Mean (pg/mL)	685	341	481	760	1623
SD (pg/mL)	858	388	641	870	1186
5th Percentile	16	14	21	12	244
95th Percentile	2593	1022	2031	2718	>4000
Percentage ≥ 100 pg/mL	80.5%	63.3%	77.9%	84.1%	100.0%
Minimum (pg/mL)	0	10	0	0	173
Maximum (pg/mL)	>4000	1651	>4000	>4000	>4000

* Representative data, results in individual laboratories may vary from these data.

A box and whiskers plot of the clinical study population, broken down by NYHA classification, is presented in the following graph. The dashed line represents 100 pg/mL, the suggested decision threshold for the AxSYM BNP assay. In support of previous literature reports,[23] these data show a progressive increase in BNP concentrations with increases in NYHA classifications. This analysis indicates that BNP measurements provide objective information for use in the assessment of the severity of heart failure.



Data from the above clinical study were used to generate the Receiver Operating Characteristic (ROC) curve of BNP decision thresholds versus clinical sensitivity and clinical specificity as shown in the following graph. At a decision threshold of 100 pg/mL, the BNP assay demonstrated a clinical sensitivity and specificity of 74.2% and 91.5% respectively, in this study. The area under the curve (AUC) is 0.90 (0.86 to 0.92, 95% CI).



The i-STAT BNP Calibrators are traceable to an internal reference standard that has been prepared gravimetrically with synthetic BNP. The internal reference standard underwent a one-time value assignment to align with the ARCHITECT BNP assay with a decision threshold of 100 pg/mL.

An age-matched analysis of the heart failure and non-heart failure populations was performed based on the data published by the American Heart Association in the 2000 Heart and Stroke Statistical Update[24] and according to the age structure of the United States population.[25] The age distributions in the intended use population are approximately as follows: individuals less than 45 years old comprise 9%, individuals 45-54 years old comprise 11%, individuals 55-64 years old comprise 22%, individuals 65-74 years old comprise 26%, and individuals 75 years and older comprise 32%. The resulting combined AUC is 0.87 (0.85 to 0.90, 95% CI).

The clinical sensitivity and specificity using a decision threshold of 100 pg/mL is presented in the following table.*

Males (Age Group)

	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sensitivity	71.0% (328/462)	47.1% (8/17)	57.1% (24/42)	57.3% (51/89)	70.6% (115/163)	86.1% (130/151)
95% Confidence Interval	66.6 to 75.1%	23.0 to 72.2%	41.0 to 72.3%	46.4 to 67.7%	62.9 to 77.4%	79.5 to 91.2%
Specificity	94.8% (403/425)	97.2% (104/107)	100.0% (71/71)	97.9% (92/94)	88.7% (102/115)	89.5% (34/38)
95% Confidence Interval	92.3 to 96.7%	92.0 to 99.4%	94.9 to 100.0%	92.5 to 99.7%	81.5 to 93.8%	75.2 to 97.1%

Females (Age Group)

	All	<45 Years	45-54 Years	55-64 Years	65-74 Years	75+ Years
Sensitivity	80.5% (186/231)	44.4% (4/9)	73.3% (11/15)	50.0% (13/26)	80.6% (58/72)	91.7% (100/109)
95% Confidence Interval	74.8 to 85.4%	13.7 to 78.8%	44.9 to 92.2%	29.9 to 70.1%	69.5 to 88.9%	84.9 to 96.2%
Specificity	88.4% (411/465)	95.9% (94/98)	90.7% (68/75)	89.6% (69.77)	85.7% (114/133)	80.5% (66/82)
95% Confidence Interval	85.1 to 91.2%	89.9 to 98.9%	81.7 to 96.2%	80.6 to 95.4%	78.6 to 91.2%	70.3 to 88.4%

* Representative data, results in individual laboratories may vary from these data.

Performance Characteristics

Precision data were collected as follows: Duplicates of each control were tested daily for a period of 20 days for each of 3 lots of cartridges, resulting in a total of 434 replicates. The average statistics are presented below.

Whole blood imprecision data were collected as follows: whole blood samples from 5 healthy donors were spiked to low, intermediate and high BNP concentrations affording 15 samples, each of which was measured in 10 i-STAT BNP cartridges from a single cartridge lot; three lots of cartridges were employed. The mean within-sample BNP concentration ranged from 84 – 3925 pg/mL and the within-sample imprecision (%CV) ranged from 3.4 to 9.4%; the average BNP concentration and imprecision were 1464 pg/mL and 6.5% respectively.

Method comparison data were collected using CLSI guideline EP9-A2.[26] Venous blood samples were collected in EDTA evacuated tubes and analyzed in duplicate on the i-STAT System. A portion of the specimen was centrifuged and the separated plasma was analyzed in duplicate on the i-STAT System and on the comparative method within 1 hour of collection. Deming regression analysis[27] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.* Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

The i-STAT BNP assay is designed for quantitation of BNP in whole blood or plasma samples. A series of samples for comparison of whole blood and plasma results was prepared from blood drawn from twenty-five nominally healthy donors. For each donor, whole blood (unspiked) and plasma obtained via centrifugation were first run simultaneously in duplicate i-STAT BNP test cartridges. A whole blood sample was then spiked with BNP and, following a short equilibration period, a plasma sample was prepared by centrifugation and the whole blood and plasma samples were run simultaneously in duplicate. Three lots of i-STAT BNP test cartridges were employed with a single lot being used for each donor. The results of Deming regression of whole blood vs plasma (x-axis) correlation data are summarized below for all samples ([BNP] < 5000 pg/mL) and separately for samples with [BNP] < 1000 pg/mL.

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*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid".[26] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (pg/mL)

Aqueous Control	Mean	%CV (within-run)	%CV (total)
Level 1	126	9.0	11.1
Level 2	1551	6.6	8.1
Level 3	3337	8.0	9.8

Method Comparison

	Abbott ARCHITECT
N	433
Mean (pg/mL)	482.1
Sxx (pg/mL)	38.1
Syy (pg/mL)	97.6
Slope	0.971
Intercept	-14.4
Sy.x	198.0
Xmin	5
Xmax	4797.7
Correlation, r	0.961

Equivalence of Whole Blood and Plasma (x-axis)

	Plasma([BNP]<5000pg/mL)	Plasma([BNP]<1000pg/mL)
N	49	36
Mean (pg/mL)	776	146
Sxx (pg/mL)	122.0	18.5
Syy (pg/mL)	98.1	16.5
Slope	0.946	1.01
Intercept	50.2	-0.2
Sy.x	107.3	28.3
Xmin	0	0
Xmax	4173	922
Correlation,r	0.997	0.996

Analytical Sensitivity

The limit of blank (commonly termed analytical sensitivity) was estimated at 14 pg/mL by calculating two times the total imprecision determined using a BNP-depleted plasma material (measured to be <5 pg/mL BNP) over a 20-day imprecision study using three separate lots of BNP cartridges and 6 i-STAT 1 analyzers.

Analytical Specificity

The BNP method is specific for the B-type natriuretic peptide. The following muscle proteins were tested at both 1000 pg/mL and 20000 pg/mL concentrations and found to have no detectable crossreactivity for BNP: ANP, CNP, and N-terminal pro-BNP.

Recovery

The dilution linearity of the i-STAT BNP test was investigated using EDTA whole blood and plasma samples derived from 3 separate donors. For each donor, the original BNP negative sample and a BNP spiked sample were prepared. This process yielded three BNP positive whole blood samples that were then assayed in duplicate for each of 3 separate i-STAT BNP cartridge lots. These whole blood samples were then diluted using an equal mass of the original unspiked whole blood and assayed in duplicate. From this whole blood data, the BNP recovery was calculated.

Whole Blood Sample	Concentration (pg/mL)	Diluted Concentration (pg/mL)	% Recovery
A	590	312	106%
B	2765	1429	103%
C	5123	2803	109%

The plasma derived from these three donors was combined in all pairwise combinations in equal volumes. These combinations were then assayed in duplicate for each of 3 separate i-STAT BNP cartridge lots. The BNP recovery for each pair was calculated using the average of the 6 results.

Plasma Blood Sample	Concentration pg/mL)	Diluted Concentration (pg/mL)	% Recovery
A	590	—	—
B	2764	—	—
C	5123	—	—
A+B	—	1570	94%
B+C	—	3992	101%
A+C	—	2734	96%

A plasma sample was spiked with BNP to a value of approximately 5000 pg/mL and the concentration was determined by duplicate measurements with i-STAT BNP test cartridges; the result was found to be within 200 pg/mL of the intended target. This sample was subjected to a series of dilutions with fresh, un-spiked plasma in order to prepare a range of concentrations. The concentration of each sample/dilution was calculated based on the measured concentration of the initial solution and the dilutions performed. The diluted samples were then measured in i-STAT BNP test cartridges (N = 6-10). The procedure was repeated with a whole blood sample. The results of these experiments are summarized in the following table.

Sample	Dilution	Calculated [BNP] (pg/mL)	Measured [BNP] (pg/mL)	%Recovery
Plasma	1	52	57	110%
Plasma	2	104	114	110%
Plasma	3	259	265	103%
Plasma	4	518	560	108%
Plasma	5	1036	1002	97%
Plasma	6	2072	2277	110%
Plasma	7	3107	3384	109%
Plasma	8	4143	4222	102%
Whole Blood	1	44	41	93%
Whole Blood	2	88	88	100%
Whole Blood	3	269	287	107%
Whole Blood	4	537	554	103%
Whole Blood	5	725	720	99%
Whole Blood	6	1450	1367	94%
Whole Blood	7	3042	2826	93%
Whole Blood	8	4056	3856	95%

Test Limitations

Partially clotted samples can result in elevated BNP readings above the reference range, as well as quality check codes. To prevent this from occurring, upon drawing the whole blood sample into a EDTA collection tube, the sample should be inverted gently at least 10 times to ensure even dissolution of the anticoagulant.

Grossly hemolyzed samples can cause a decreased alkaline phosphatase activity, resulting in decreased detection of BNP, increased assay backgrounds, and/or quality check codes.

Hematocrits in the range of 0-60 %PCV have been demonstrated not to affect results. Samples with hematocrit levels above this range have demonstrated increases in the test imprecision and quality check codes.

The analyzer must remain on a flat surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.

Measurements of BNP should occur prior to nesiritide (Natrecor) recombinant BNP treatment, or 2 hours post-treatment.[28]

Storage Instructions

Please see the "Shelf Life" and "Preparation for Use" sections on page 1 of the Cartridge and Test Information section of the i-STAT 1 System Manual.

Quality Control

On a daily basis, the performance of all Analyzers in the i-STAT System on site should be verified using the i-STAT Electronic Simulator.

On receipt of new cartridges, verify that the transit temperatures were satisfactory using the four-window temperature indicator strip included with the cartridge boxes. From each shipment of cartridges, analyze multiple levels of i-STAT BNP Controls using any verified i-STAT 1 Analyzer. These controls should also be used to verify cartridge performance when storage conditions are in question.

For additional information on Quality Control of the i-STAT System, refer to the "Quality Control" section of the i-STAT 1 System Manual.

Specimen Collection and Preparation

i-STAT BNP cartridges require the use of EDTA whole blood or plasma samples collected in plastic syringes or evacuated tubes containing EDTA. The use of glass vessels is not recommended because the BNP molecule has been shown to be unstable in glass tubes.[29,30]

The use of whole blood or plasma samples containing other anticoagulants such as oxalate and citrate will cause deactivation of the alkaline phosphatase, resulting in decreased BNP readings. Performance characteristics have not been established for samples taken from capillary tubes and direct skin punctures (e.g. fingersticks) so these sample types should not be used with the BNP cartridge.

The i-STAT BNP cartridge requires a minimum sample volume of 17 μL to fill. Excess amounts beyond this requirement will not impair the results. However, excess blood or plasma will be present at the inlet of the cartridge and caution should be observed in handling the cartridge to minimize biohazard exposure.

When drawn into an evacuated tube containing EDTA, samples should not be used unless the blood collection tube is filled at least half full.

For best results, samples must be mixed well before transfer to a cartridge. Immediately after filling the cartridge, the sample port should be closed and the cartridge inserted into the analyzer.

Interference Testing

The following substances were found to have no significant effect (less than 10%) on the BNP method, when added to a plasma pool containing approximately 1000 pg/mL of B-type natriuretic peptide at the concentrations indicated:

Interference studies were based on CLSI guideline EP7-A.[31]

Compound	Test Level (μmol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ampicillin	152
Ascorbic Acid	227
Acetyl Salicylic Acid	3333
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155
Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin	90 U/mL
Ibuprofen	2425
Isosorbide dinitrate	636
Methyldopa	71
Nicotine	6.2
Nifedipine	1.156
Phenytoin	198
Propanolol	7.71
Salicylic Acid	4.34
Theophylline	222
Verapamil	4.4
Warfarin	64.9

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i-STAT®
TECHNICAL BULLETIN

ANALYZER CODED MESSAGES

From the time it powers up until the time it powers down, the i-STAT® Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause", an "action" message, and a code.

The Cause Message:

This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".

The Action Message:

This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.

The Cause Code:

This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Services or your local support organization for further assistance. The codes are stored in the analyzer's memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.

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Code Number	Cause/Action Message on Display	Explanation
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
3	**New Software Installed** / Use Electronic Simulator	This message appears on the Portable Clinical Analyzer after new software has been installed or, in some cases, when a new customization profile is received.
4, 8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
5, 6, 9	**Analyzer Interrupted** / Ready for Use	The Portable Clinical Analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down. Check that batteries are inserted properly and seated well in the analyzer. Batteries that are too short will not make proper contact. Check the battery voltage on the Status Page.
7	**Batteries Changed** / Ready for Use	This is a normal response on the Portable Clinical Analyzer when the batteries are changed after a code 1 has occurred.
10	**Temperature In Range** / Ready for Use	Temperature is back in range following a code 2 on the Portable Clinical Analyzer.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Invalid or Expired CLEW** / See Manual	The CLEW standardization has expired. Download a valid CLEW. The date on the real time clock exceeds the expiration date of the CLEW software. Check the date on the real time clock.
13	**Invalid or Expired CLEW** / See Manual	The CLEW is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Retransmit the customization profile. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
15	**Barcode Does Not Match Cartridge Type**	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

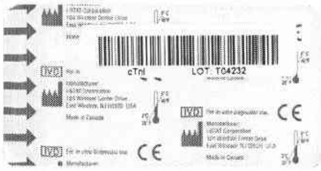
The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may an analyzer problem.

Code Number	Cause/Action Message on Display	Explanation
19	**No Clot Detetced** / See Manual	During the PT/INR cycle, no clot was detected. Run another cartridge. If code 19 reappears, run the sample on an alternate methodology.
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization.
26	**Cartridge Error** / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27-29, 32, 33, 40, 41, 45, 87	**Cartridge Error** / Use Another Cartridge	These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, and 41 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin.
42, 43	**Cartridge Error** / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
35, 36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample** / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
49	**Poor Contact Detected** / See Manual	The system detected a contact problem with one of the connector pins while reading the identification chip in the immunoassay cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
23, 53, 55, 63, 65-68, 70, 72-74, 82, 85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover. Code 23 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. Code 70 can occur on the Portable Clinical Analyzer if the user presses the DIS key before the Electronic Simulator is run after a software update. If this happens, reseat the batteries to reset the analyzer, and then run the Electronic Simulator. Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzer. If these codes persist, contact i-STAT Technical Services or your local support organization for further assistance. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact i-STAT Technical Services or your local support organization for further assistance.
69	**Cartridge Type Not Recognized** / Use Another Cartridge	This code could be due to use of a cartridge type that is not compatible with the version of software in the analyzer, or the use of expired cartridges. Check the cartridge expiration date on the cartridge box or pouch. If the cartridges have not expired, and if a new cartridge type is being run, contact i-STAT Technical Services or your local support organization for a software update. When running coagulation cartridges, Code 69 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. During immunoassay cartridge runs, this code will be displayed if incorrect information is entered in response to the prompt "Enter or Scan Cartridge Lot Number". The instrument expects the barcode on the back of the individual cartridge portion pack to be scanned. The correct barcode looks like this:  For immunoassay cartridges, the instrument will not accept keypad entries of the cartridge lot number nor a scan of the barcode on the cartridge box. This condition may be due to an aberrant cartridge. However, if the condition occurs repeatedly on one analyzer, the analyzer may need repair. Contact i-STAT Technical Services or your local support organization for further assistance.

Codes 100-111 indicate a condtion with the PCx or PCx Plus Glucose Test Strip on the i-STAT 1 Analyzer

Code Number	Cause/Action Message on Display	Explanation
100	**Strip Error** / Use Another Strip	The user tried to run a wet strip. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
101	**Strip Error** / Use Another Strip	The test strip was removed from the strip port during testing. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
103, 105, 106, 107, 111	**Strip Error** / Use Another Strip	Test unsuccessful. An error was detected during the analysis sequence. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test. If the problem persists, record the three digit error code and contact Abbott Diabetes Care support services or your local support organization.
102, 104	**Strip Error** / Use Another Strip	The test strip malfunctioned or the blood glucose level in the sample is beyond the measuring capability of the test strip and strip reader. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test with a new test strip. If the error occurs again, confirm the result by performing the test on a different method. Contact Abbott Diabetes Care support services or your local support organization.
108, 109	**Temperature Out of Range** / Check Status Page	During the test, room temperature became unstable or moved outside the limits within which the test strip reader can perform a test. Ensure that the room temperature is within the specified limits. Allow the analyzer to stabilize to a room temperature of 15-40°C or 59-104°F. Press the Menu key until the Administration Menu is displayed. Press 1 for Analyzer Status where the room temperature reading is displayed. If the temperature reading on the Status Page is within the limits described above, yet these codes persist, there may be a problem with one of the thermistors in the analyzer. Contact i-STAT Technical Services or your local support organization for further assistance.
110	**Strip Error** / Use Another Strip	At the start of the test strip cycle, the analyzer prompts the user to apply blood to the strip and waits for 20 minutes for the user to do so. This error occurs when the 20 minutes have elapsed and the analyzer didn't detect blood. The most likely cause of this error is lack of user interaction.

Codes in the range of 120 to 138 and 140 to 151 indicate a failure during an immuno cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used. Only the i-STAT 1 Analyzer produces these codes, as the Portable Clinical Analyzer does not support immuno cycles.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144, 148	**Cartridge Error** / Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error** / Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	**Cartridge Error** / Use Another Cartridge	This code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.
127	**Cartridge Error** / Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.
128, 131, 132, 134, 135 - 138	**Cartridge Error** / Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. **Discard** *(always)* 1 drop from delivery device to clear unseen bubbles. 2. **Hang** single drop slightly larger than round target well. 3. **Touch** one drop *(only)* to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of RED FILL LINE diagram. 5. **Close** slide cover from left to right. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge closure between your first finger and thumb. There is a recess for your thumb in the closure. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error** / Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error** / Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.
140	**Lot Expired**	The analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.

Code Number	Cause/Action Message on Display	Explanation
141	**Test Canceled by Operator**	This code will be displayed if the cartridge barcode is not scanned within 60 seconds of cartridge insertion. The correct barcode to scan is the barcode on the cartridge portion pack, not the one on the cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above.
145	**Cartridge Error /** Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • cartridge leak, • failure to close the cartridge completely. Ensure that the slide cover is fully engaged before inserting the cartridge into the analyzer • underfilled cartridge. Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the "fill to" mark, and then close the cartridge.
146	**Cartridge Error /** Use Another Cartridge	Overfilled cartridge. Repeat the test.
147	**Analyzer Error /** See Manual	In order to run an immunoassay cartridge, the i-STAT 1 Analyzer must: • bear the i immuno symbol and • be customized for a) Cartridge Barcode Required, or b) Cartridge Information First Required and Cartridge Lot Number Required. If either of these two conditions above are not met, the analyzer will display this code.
149 - 151	**Cartridge Error /** Use Another Cartridge	The analyzer detected an atypical data stream from the analyzer. Try another cartridge.

The following conditions are related to the Electronic Simulator

Code	Explanation	How to Respond
Numerical Code	See under Analyzer Coded Messages.	See under Analyzer Coded Messages.
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Allow analyzer to equilibrate in new environment for 30 minutes and repeat test. If code reoccurs, return anlayzer.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Reinsert the simulator straight. If code reoccurs, return analyzer.
R, r	Resistance reading on conductometric channel out of limits.	Return analyzer.
t	Thermal probe failure.	Return analyzer.
B	Potentiometric channel out of limits.	Return analyzer.

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact i-STAT Technical Services or your local support organization for further assistance.

PROCEDURE FOR USING AN i-STAT CERAMIC CONDITIONING CARTRIDGE (CCC) FOR ANALYZER PIN CONDITIONING

Step Number	Explanation
1. Run an external Electronic Simulator.	If the analyzer is configured with the internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the internal Simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.
2. Run the CCC two times.	Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.
3. Update the CCC Usage Log	The log is located on page 3 of the Technical Bulletin entitled "Instructions for Restoring Analyzers That Produce *** for Hematocrit and Quality Check Code 23", which is shipped with the CCC. Updating the log allows the user to keep track of the number of pin conditioning cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use.
4. Return the analyzer to service.	

i-STAT®
TECHNICAL BULLETIN

Proficiency Testing on the i-STAT® System

Proficiency Testing

CLIA regulation *Subpart H – Participation in Proficiency Testing* requires a laboratory to enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services (CMS) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in *Subpart I – Proficiency Testing Programs*.

A primary testing system is defined as the only method or the primary method for performing and reporting tests under a CLIA certificate. The i-STAT System may be a primary testing system when:

- A hospital has separate CLIA certificates for the main laboratory and point of care testing;
- A hospital owns a clinic, same-day surgery, kidney dialysis unit, etc., which requires a separate CLIA certificate;
- The i-STAT System is the hospital's primary laboratory testing system; or
- The i-STAT System is the main testing system in a physician's office, skilled nursing facility, unaffiliated patient transport service, homehealthcare agency, etc.

For CLIA regulated analytes, proficiency testing (PT) programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must handle samples as they would patient samples and return the results within a specified time to the provider for grading.

The i-STAT System

The i-STAT System consists of any number of i-STAT Portable Clinical Analyzers, i-STAT 1 Analyzers and Philips Medical Systems Blood Analysis Modules (collectively known as the "Analyzer"). All Analyzers that pass the Electronic Simulator test are equivalent. Therefore, PT samples can be tested on any Analyzer that has passed the Electronic Simulator test.

It is recommended that the Proficiency Test path be used on the i-STAT Portable Clinical Analyzer and the i-STAT 1 Analyzer when testing proficiency samples that include hematocrit. The Proficiency Test path uses the K_3EDTA standardization coefficients for hematocrit; use of this test path will ensure that results from analyzers customized for K_2EDTA will match results from analyzers customized for K_3EDTA for survey reporting purposes. (If the Proficiency test path is not used and the analyzer is customized for K_2EDTA, the displayed result should be divided by 1.0425 before reporting.) Do not select CPB as a sample type.

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- To access the Proficiency Test path on the Portable Clinical Analyzer:
    1. Insert the Electronic Simulator and wait for PASS to be displayed.
    2. Hold down the DIS key and press the MENU key to access the Utility menu.
    3. Press 5 for Proficiency.
- To access the Proficiency Test path on the i-STAT 1 Analyzer
    1. Press the On/Off key.
    2. Press the MENU key.
    3. Press 3 for Quality Tests.
    4. Press 2 for Proficiency.

PT programs for the i-STAT System

There are several national CMS approved PT program providers such as the College of American Pathologists (CAP), the American Association of Bioanalysts (AAB), the American Proficiency Institute (API) and WSLH PT. Several states have CMS approved PT programs as well. Each of these providers has several PT surveys to choose from. In general, aqueous-based PT surveys are recommended for blood gas and electrolyte testing on the i-STAT System.

Certain PT survey samples are not compatible with i-STAT System sensors and may contain interfering substances that could affect results. Fluorocarbon samples for blood gases and fixed-cell samples for hematocrit are not compatible with the sensors.

Continuous cartridge manufacturing process improvements made by Abbott Point of Care i-STAT necessitate re-establishing associated standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. Coefficients in the System software ensure that whole blood results from all cartridge types will be equivalent. However, results from aqueous samples may differ between older and newer generations of cartridges. Some of these differences may be significant. Abbott Point-of-Care i-STAT will continue to work with PT providers to prevent i-STAT System users from being unfairly penalized for PT failures that can be attributed to manufacturing improvements.

Please note that the list of PT providers included at the end of this Technical Bulletin is only a guideline. It is neither an exhaustive list, nor an endorsement of any particular PT provider. The information contained in this Technical Bulletin is correct as of the publication date, and users should contact PT providers for further information.

It is important that the correct **Instrument/Method Code** be reported on the survey result form. The choice of code **for the blood gas and chemistry analytes,** where applicable, must be based on the **cartridge type** used, as detailed in the table below:

i-STAT Thermal Cartridges	i-STAT Non-Thermal Cartridges
CG4+	6+
CG8+	E3+
Crea	EC4+
EG6+	EC8+
EG7+	G
G3+	
CHEM8+	

CK-MB and BNP

The Plasma Cardiac Markers (PCM) survey from API is suitable for the i-STAT System CK-MB and BNP, as well as cTnI cartridges.

PT materials from CAP and WSLH are being evaluated for possible introduction as standard PT materials for CK-MB and BNP on the i-STAT System.

The i-STAT CHEM8+ Cartridge

The College of American Pathologists (CAP) began offering TCO_2 as a reportable analyte in the AQ/AQ2 Surveys in 2006. The American Proficiency Institute (API) began offering TCO_2 as a reportable analyte in their i-STAT Chemistry Survey in 2006. WSLH PT will offer TCO_2 as a reportable analyte in the Blood Gas "Plus" for i-STAT (BP) survey in 2007. Therefore, in 2007, CAP's AQ and AQ2 surveys, API's i-STAT Chemistry survey, and WSLH PT's BP survey can be used for all of the CHEM8+ analytes. Please note that the CHEM8+ analyte results are reported using the thermal cartridge Instrument/Method Code number, where applicable.

Proficiency Providers

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
College of American Pathologists (CAP)			
College of American Pathologists (CAP) 325 Waukegan Road Northfield, IL 60093-2750 800-323-4040 or 847-832-7000 www.cap.org	CAP AQ and AQ2 surveys for blood gases and electrolytes LN13 Blood Gas/ Electrolytes/Cal Ver/ Linearity XL/XLN Excel Series Blood Gas/Electrolytes	*Instrument Codes:* *1927: i-STAT thermal cartridges.* *1928: i-STAT non-thermal cartridges.*	For consistency of hematocrit results across sites, use the PT pathway and do NOT select the CPB sample type. According to the AQ and AQ2 survey instructions, *P*O2 results should not be corrected for barometric pressure. **The barometric pressure should be reported with the uncorrected results.** Barometric pressure can be reported from the Status Page after the results are displayed.
	CAP CT1 and CAP EXCEL XC8 surveys for Activated Clotting Time (ACT)	*Instrument Code: i-STAT Kaolin ACT: 2058* *Instrument Code: i-STAT Celite ACT: 2085*	Samples are reconstituted with 0.025 mol/L (25 mmol/L) calcium chloride **supplied by the user.**
	CAP Plasma Cardiac Markers (PCARM) Survey XL/XLN Excel Series Troponin I Module L30	Instrument Code: 3277: i-STAT	For use with the i-STAT cTnI cartridges only.
	Whole Blood PT/INR (WP3)	N/A	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
American Association of Bioanalysts (AAB)			
American Association of Bioanalysts (AAB) AAB Proficiency Testing Service 205 West Levee St. Brownsville, Texas 78520 800-234-5315 www.aab.org	Activated Clotting Time	*Method Code: i-STAT Kaolin ACT: 600* *Method Code: i-STAT Celite ACT: 602*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Whole Blood Prothrombin Time	*Method Code: i-STAT PT/INR Cartridge: 600*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Basic Chemistry	*Instrument and Reagent Code: 145*	
	Blood Gases	Method Codes: 145: i-STAT thermal cartridges. 146: i-STAT non-thermal cartridges.	
	Hematology (for Hct and Hb only)	Method Codes: 150: i-STAT thermal cartridges. 151: i-STAT non-thermal cartridges	For consistency of hematocrit results across sites, use the PT pathway and DO NOT select the CPB sample type.
American Proficiency Institute (API)			
American Proficiency Institute (API) 1159 Business Park Drive Traverse City, MI 49686 800-333-0958 www.api-pt.com	i-STAT Chemistry (including Blood Gases) – Catalog #145	Method (Cartridges): • i-STAT thermal cartridges • i-STAT non-thermal cartridges	For consistency of hematocrit results across sites, use the PT pathway and do NOT select the CPB sample type.
	i-STAT ACT (Activated Clotting Time) – Catalog #215	*Method (Cartridges):* • Celite ACT Cartridge • Kaolin ACT Cartridge	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	i-STAT Protime – Catalog #216	*N/A*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Plasma Cardiac Markers (PCM) - Catalog #157 (five samples) - Catalog #159 (two samples)	*N/A*	For use with i-STAT cTnI, CK-MB, and BNP cartridges.

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
WSLH PT			
WSLH PT 465 Henry Mall Room 402 Madison, WI 53706 800-462-5261 www.wslhpt.org	Activated Clotting Time (CTO)	*Method Code: i-STAT Kaolin ACT: 3673* *Method Code: i-STAT Celite ACT: 3672*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Blood Gases/Electrolytes (BG) Blood Gases "Plus" for i-STAT (BP) Non-Blood Gas Analytes for i-STAT (NBG)	Method (Cartridges): • i-STAT non-thermal cartridges: 3676 • i-STAT thermal cartridges: 3677	For consistency of hematocrit results across sites, use the PT pathway and do NOT select the CPB sample type.
	i-STAT Protime/INR (PRC)	*N/A*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Cardiac Markers – 5 sample (IE) Cardiac Markers – 3 sample (TM)	*Method Code: i-STAT cTnI: 3670*	For use with i-STAT cTnI cartridges only. Survey CP is also compatible, but IE/TM is recommended for adequate i-STAT peer group statistics.
California Thoracic Society			
California Thoracic Society 202 Fashion Lane Suite 219 Tustin, CA 92780 714-730-1944 www.thoracic.org/chapters	Blood Gas / Electrolyte Survey (BG)	Method Codes for: • i-STAT Non-thermal Cartridges: 3676 • i-STAT Thermal Cartridges: 3677	
AccuTest Inc.			
AccuTest Inc. P.O. Box 999 7 Hayrick Lane Westford, MA 01886-0031 800-665-2575 www.digitalpt.com	Blood Gas / Electrolytes (BGAS435) and Blood Gas / Electrolytes POC (PBGA432)	N/A	
	Basic Chemistry (BCHE435)	N/A	
	Hematocrit (HCRT435) and Hematocrit POC (PHCR432) *(Hematocrit by conductivity methods survey only)*	N/A	For consistency of hematocrit results across sites, use the PT pathway and do NOT select the CPB sample type.
	Urea / Creatinine (URCR435) & Urea / Creatinine POC (PUCR432)	N/A	

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
HealthMetrx Canada Inc. (CANADA ONLY)			
HealthMetrx Canada Inc. (CANADA ONLY) 307-2083 Alma St. Vancouver, BC V6R 4N6 Canada 800-665-7436 www.digitalpt.com	Blood Gas / Electrolytes (BGAS435) and Blood Gas / Electrolytes POC (PBGA432)	N/A	
	Routine Chemistry (CHEM463)	N/A	
	Hematocrit (HCRT435) and Hematocrit POC (PHCR432) *(Hematocrit by conductivity methods survey only)*	N/A	For consistency of hematocrit results across sites, use the PT pathway and do NOT select the CPB sample type.
	Urea / Creatinine (URCR435) & Urea / Creatinine POC (PUCR432)	N/A	
New York State Department of Health			
New York State Department of Health Wadsworth Center P.O. Box 509 Albany, NY 12201-0509 518-485-5378 www.wadsworth.org	Blood pH and Gases	*i-STAT Instrument Code: IAA*	
	Clinical Chemistry	i-STAT Instrument Code: IAA Reagent Code: • i-STAT non-thermal cartridges: IA2 • i-STAT thermal cartridges: IA1	

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
Medical Laboratory Evaluation (MLE)			
Medical Laboratory Evaluation (MLE) 2011 Pennsylvania Avenue, NW Suite 800 Washington, DC 20006-1834 800-338-2746, option 5 www.acponline.org/mle email: mle@acponline.org	i-STAT Chemistry 1 - Catalog #817 (includes #818 & 847)	i-STAT Instrument Code: 893	Now includes CO_2
	i-STAT Chemistry 2 - Catalog #818	i-STAT Instrument Code: 893	Now includes CO_2
	Blood Gases - Catalog #847	Method Code: 893	Samples do not contain fluorocarbons
	i-STAT Protrombin Time - Catalog #328	i-STAT Instrument Code: 229	Samples are reconstituted with calcium chloride provided by the Proficiency Provider.
American Academy of Family Physicians - Proficiency Testing Program (AAFP - PT)			
American Academy of Family Physicians Proficiency Testing Program (AAFP-PT) 11400 Tomahawk Creek Parkway Leawood, Kansas 66211-2672 800-274-7911 www.aafp.org/pt email: pt@aafp.org	Module 700 - i-STAT Chemistry	N/A	Includes sodium, potassium, chloride, BUN, creatinine, glucose, hemoglobin and hematocrit.
	Module 702 - Blood Gases	N/A	Includes pH, PCO_2, PO_2, and iCa.
	Module 748 - i-STAT Protime	N/A	

i-STAT®
TECHNICAL BULLETIN

Hematocrit Determination in the i-STAT® System and Comparison To Other Methods

This bulletin describes the four most common methods for determining hematocrit (microhematocrit, conductometric, and as calculated by automated cell counters and co-oximeters) and the common interferences, which lead to discrepancies among the four methods.

The i-STAT System uses the conductivity method to determine hematocrit. The Point-of-Care Testing Coordinator should ensure that end users are aware of factors affecting results obtained on the i-STAT System. Factors affecting hematocrit results are included in this Technical Bulletin.

HEMATOCRIT

CLSI recommends that the term hematocrit be used to describe the materials and/or method used to measure Packed Cell Volume (PCV).[1] PCV is defined as the measure of the ratio of the volume occupied by the red cells to the volume of whole blood in a sample of capillary, arterial or venous blood. This ratio is measured after appropriate centrifugation and is formally expressed as a decimal fraction.

Abbott Point of Care Inc. has retained the term hematocrit for the measured quantity and, according to common practice, expresses hematocrit as a percentage, in units of Percent Packed Cell Volume (%PCV). A hematocrit of 0.45 PCV is expressed as 45 %PCV.

THE METHODS

The Microhematocrit Method

Microhematocrit is the standard method for hematocrit determination[1]. An anticoagulated sample in a microcapillary tube is spun in a centrifuge. The red blood cells are separated from the plasma by the centrifugal force. The height of the separated red blood cell column is compared to the height of the entire sample column to determine the packed cell fraction (*i.e.*, the hematocrit).

The hematocrit of a sample can be altered by the anticoagulant. It is well documented that K_3EDTA causes the cells to shrink by increasing the osmotic pressure in the plasma[1,2,3,4], thus reducing the hematocrit below its value *in-vivo*. Current literature indicates that the hematocrit is reduced between 1.5 %PCV and 2.2 %PCV at normal hematocrit levels. Experiments conducted by Abbott Point of Care Inc. indicate a shrinkage of about 2 %PCV at normal hematocrit levels. For more information, please see the Technical Bulletin "K_2EDTA and K_3EDTA Customization for Hematocrit on the i-STAT System" (716240-00B).

Conductivity Methods

Systems using the conductivity method, such as the i-STAT System, measure the electrical conductance of a whole blood sample. Plasma conducts electrical current, and blood cells act as insulators. A sample with a relatively high hematocrit has, by definition, a larger proportion of its volume filled by the non-conductive red blood cells. The overall conductance of the sample will thus be relatively low. In the i-STAT System, before the measured sample conductance is converted into a hematocrit value, corrections are applied for the temperature of the sample, the size of the fluid segment being measured, and the relative conductivity of the plasma component. The first two corrections are determined from the measured value of the calibrant conductance; the last correction is determined from the measured concentrations of sodium and potassium in the sample.

Most hospital laboratories use automated hematology analyzers as the primary systems for hematocrit determinations and it is common practice for these analyzers to be calibrated to match the microhematocrit method for samples anticoagulated with K_3EDTA. To minimize confusion at the majority of institutions where the i-STAT System is used, the i-STAT System is calibrated to match microhematocrit determinations on samples anticoagulated with K_3EDTA. While samples for the i-STAT System are collected in lithium heparin, results may be reported in terms of either K_3EDTA or K_2EDTA calibration. Agreement between methods is achieved by selecting the appropriate customization setting on the i-STAT System.

Automated Hematology Analyzer Methods

Automated hematology analyzers do not directly measure hematocrit, but rather calculate hematocrit from measurements of individual cell sizes and counts. The sample is diluted with an isotonic buffered aqueous solution and passed through a measuring orifice. Individual cells are counted and sized by one of two basic mechanisms. Either fluctuation in electrical conductivity or the scatter of collimated light, is measured as cells pass through the orifice. The hematocrit of the original sample is calculated from the number of cells, the sizes of the cells and the volume of diluted solution passing through the orifice.

Co-oximetry Methods

Like hematology analyzers, co-oximeters do not directly measure hematocrit. Hematocrit values are calculated from hemoglobin values that are measured by spectrophotometry. A fixed relationship between hemoglobin and hematocrit is used to calculate hematocrit.

METHOD COMPARISONS

The discrepancy between the hematocrit values determined by two different systems on an individual sample has three components: a random component, a systematic component and a method-dependent / sample-specific component.

Random Component

The random component results from the combination of each system's imprecision. The size of the component is different on each determination. The imprecision of the i-STAT System is typically about 0.6 %PCV to 0.7 %PCV (1 standard deviation).

Systematic Component

The systematic component results from differences in the systems' calibration, and is constant from sample to sample.

Method-Dependent / Sample-Specific Component

The method-dependent / sample-specific component results from the specific interferences which affect different measurement methods. Each sample has specific characteristics, which may cause different methods to have different types and sizes of measurement error.

The method-dependent / sample-specific component is commonly observed as a random difference between dissimilar methods. It can, however, also cause an apparent systematic difference component when a particular sample population has a systematic characteristic. For example, a population of samples with low mean cell hemoglobin concentration (MCHC) will cause a systematic negative bias on determinations by some automated hematology analyzers when compared to determinations from both microhematocrit and conductivity systems.

LIMITATIONS OF THE METHODS

Microhematocrit

Sources of error in the microhematocrit method are discussed in the Procedure for Determining Packed Cell Volume by the Microhematocrit Method,[1] and include sampling, tube, reading and packing errors.

Conductivity Methods

Electrolyte Concentration

The conductivity of the whole blood sample is dependent upon the concentration of electrolytes in the plasma portion. The i-STAT System corrects for the concentration of electrolytes using the measured value of sodium and potassium. The interference is minimized to an insignificant level.

Other Non-Conducting Elements[33-38]

The conductivity method does not distinguish red blood cells from other non-conducting elements such as proteins, lipids and white blood cells, which occupy volume in the sample. The i-STAT System is calibrated to read hematocrit accurately when these other elements are at normal levels.

Total Protein

At hematocrit levels less than 40 %PCV, the reading will increase by approximately 1 %PCV for each g/dL (10 g/L) the protein level is increased outside the normal range of 6.5 g/dL to 8.0 g/dL (65 g/L to 80 g/L). At hematocrit levels less than 40 %PCV, the reading will decrease by approximately 1 %PCV for each g/dL (10 g/L) the protein level is decreased outside the normal range of 6.5 g/dL to 8.0 g/dL (65 g/L to 80 g/L). At hematocrit levels greater than 40 %PCV the interference is about three quarters that size.[39]

It is important to be aware of the total protein level when using conductivity systems to monitor a patient on a cardiopulmonary bypass pump.[38] If albumin, or other colloid, is not added to the pump's priming solution, the plasma protein will drop by about 3 g/dL to 4 g/dL (30 g/L to 40 g/L). The conductivity reading will then be systematically low by 3 %PCV to 4 %PCV. For further information on the use of the coronary bypass mode on the i-STAT System see the Theory section of the i-STAT or i-STAT 1 System Manual.

It is also important to be aware that the total protein level in premature neonates can be in the range of 3.6 g/dL to 6.0 g/dL (36 g/L to 60 g/L).[40] Total protein levels may be low in burn patients and in patients receiving large volumes of saline-based fluids.

Lipids

Interference from lipids will be about two-thirds the size of the interference from proteins. The protein interference is larger because it is a charged non-conducting element.

White Blood Cells

Interference from white blood cells depends upon the size of the cell. As an example, the hematocrit reading will be increased by 1 %PCV when the white cell count is 50,000 per microliter, assuming the average white blood cell occupies twice the volume of an average red blood cell.

Automated Hematology Methods

Osmolality:[16-27]

Abnormal sample osmolality can create discrepant readings as the red cells shrink or swell to achieve osmotic balance with the isotonic (normal osmolality) diluent. Differences up to 10 %PCV have been reported for glucose concentrations in the range of 1000 mg/dL to 2000 mg/dL. Differences up to 5 %PCV have been reported for samples with low or high sodium concentrations.

Cold Agglutinins:[28-32]

Under the right conditions of diluent temperature, red blood cells from certain samples will clump together. The large clumps will not be recognized as red blood cells by certain automated hematology analyzers, and thus the overall red blood cell count and the calculated hematocrit, will be falsely low. In extreme cases, the hematocrit can read low by up to about 8 %PCV.

Mean Cell Hemoglobin Concentration:[11-15]

Red blood cells can deform under the pressure experienced when being sent through the measuring orifice. This is particularly true for electrical impedance methods. Cells with lower hemoglobin concentrations will deform to a greater degree. This can create errors as large as 3 %PCV.

Early authors attributed the discrepancy between automated hematology determinations and reference microhematocrit determinations to variabilities in trapped plasma on the microhematocrit determination.[5-9,10a,10b] Recent authors have recognized the substance of the discrepancy to be an interference on the automated method.

Co-oximetry Methods

The accuracy and precision of measured total hemoglobin from co-oximeters depends on the instrument's efficiency in hemolyzing the blood and the number of wavelengths used to determine hemoglobin. The calculation of hematocrit from measured hemoglobin assumes a normal MCHC. Deviation from a normal adult MCHC, e.g. in children, may give an inaccurate calculated hematocrit.[41] Other limitations of measuring total hemoglobin by spectrophotometric methods include the effect of sulfhemoglobin and fetal hemoglobin and hyperlipidemic plasma that may falsely elevate the hemoglobin.[42,43] An extremely high number of WBCs may also elevate the hemoglobin value resulting in an inaccurately calculated hematocrit.[44]

Standards for Microhematocrit Determination

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TECHNICAL BULLETIN

Installation Guide For The Central Data Station To Receive Data From A Philips Clinical Data Server*

The i-STAT Central Data Station (CDS) application can be configured to receive results from cartridges analyzed on a Philips Medical Systems (formerly Agilent Technologies) Blood Analysis Module (BAM) for the CMS and 24/26 Patient Monitors. This data is sent to the CDS by the Philips Clinical Data Server (Philips). This document describes how to set up the i-STAT CDS application to receive data from the Philips Clinical Data Server. It is independent of the computer hardware platform being used.

CONFIGURATION INSTRUCTIONS

This guide assumes that the Philips Clinical Data Server connectivity to the location of the CDS computer is completed, and that the Philips Clinical Data Server data is available via one of these two protocols:

- A direct RS-232 serial connection
- An Ethernet connection to a ETS 8 Terminal Server (CDS 4.x) or a Network Interface Card (CDS5.x)

To configure the CDS 5.x:

Step	Action
1	Run the CDS application (wcds32.exe) with the "config" command line parameter.
	The remainder of the configuration is dependent on the connection of the Philips Clinical Data Server to the CDS.

For Philips Clinical Data Server data received via a direct RS-232 nnection:	
2	Determine which COM Port of the CDS computer is to be used for the Philips Clinical Data Server data.
3	At the Serial Ports tab page, select "Enable Serial Communications". Add the COM Port to be used for the Philips Clinical Data Server to the "Configured Ports" list, select Agilent Connect as instrument type, and click "Accept".
4	Connect the cable to the appropriate COM Port on the CDS computer.
5	Verify that the Philips Clinical Data Server data is being received.

For Philips Clinical Data Server data received via a Network Interface Card:	
2	At the Network tab page, select "Enable Network Communications". Note the default of 6002 for Agilent Connect TCP port, change if neccessary. Click "Accept".
3	Verify that the Philips Clinical Data Server is configured to transmit to the specific port noted in step 2 at the CDS IP network address.
4	Verify that the Philips Clinical Data Server data is being received.

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To configure the CDS 4.x:

Step	Action
1	Determine which COM Port of the CDS computer is to be used for the Philips Clinical Data Server data.
2	Using the Configuration Utility of the CDS, change the data source of this COM Port to the "CDS" option.
3	Exit the Configuration Utility.
	The remainder of the configuration is dependent on the form of the Philips Clinical Data Server data.

For Philips Clinical Data Server data received via a direct RS-232 connection:	
4	Determine the communication speed of the Philips Clinical Data Server. Ideally, it should be set at 19200 baud.
5	If set to 19200, use any text editor to edit the file C:\istatcds\istatcfg.txt. Add the following line to the section with the heading of **[Options]:** **FastCdsSend=YES** Save the file and exit the Text Editor. If set to 4800, no changes are needed
6	Connect the cable to the appropriate COM Port on the CDS computer.
7	Verify that the Philips Clinical Data Server data is being received.

For Philips Clinical Data Server data received via an ETS 8 Terminal Server:	
4	Determine which serial port on the ETS 8 will be used for the Philips Clinical Data Server transmission.
5	Verify that the Philips Clinical Data Server is configured to transmit to that specific port at the ETS 8 Ethernet address
6	Verify that the port of the ETS 8 is configured for 19200 baud.
7	Using any text editor, edit the file C:\istatcds\istatcfg.txt. Add the following to the section with the heading of **[Options]:** **FastCdsSend=YES** Save the file and exit the Text Editor.
8	Connect the cable from the selected ETS 8 serial port to the selected COM port on the on the CDS computer.
9	Verify that the Philips Clinical Data Server data is being received.

K_2EDTA and K_3EDTA Customization for Hematocrit on the i-STAT® System

PURPOSE

This Technical Bulletin contains the information needed to select the K_2EDTA or K_3EDTA customization option for reporting hematocrit results on the i-STAT System.

HEMATOCRIT CALIBRATION

The reference method for hematocrit is the microhematocrit (MH) method. All instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference method.[1-3]

The microhematocrit reference method described in CLSI H7-A3[3] permits both K_2EDTA and K_3EDTA anticoagulant sample collection tubes. K_3EDTA anticoagulant shrinks red blood cells relative to K_2EDTA anticoagulant, causing microhematocrit results from K_3EDTA samples (MH-K_3EDTA) to be lower by approximately 2 – 4% than results from K_2EDTA samples (MH-K_2EDTA).[3,4]

Consequently, instruments calibrated to MH-K_3EDTA report lower hematocrit results than analyzers calibrated to MH-K_2EDTA.

SELECTION OF THE K_2EDTA OR K_3EDTA CUSTOMIZATION SETTINGS ON THE i-STAT SYSTEM

i-STAT provides two customization settings for reporting hematocrit results: The "K_3EDTA" customization reports hematocrit results traceable to MH-K_3EDTA. The "K_2EDTA" customization reports hematocrit results traceable to MH-K_2EDTA.

For best agreement of i-STAT and hematology analyzer hematocrit results, the i-STAT customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K_2EDTA or MH-K_3EDTA).

i-STAT has verified with the manufacturers of the Advia®, Cell-Dyn®, Coulter® and Sysmex® hematology analyzers that hematocrit results on these analyzers are calibrated to MH-K_3EDTA. Because these hematology analyzers report hematocrit results calibrated to MH-K_3EDTA and are representative of the hematology market, "K_3EDTA" was chosen as the factory default customization setting for the i-STAT System.

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When the calibration of a comparative method is uncertain, determine the customization setting by minimizing the average bias between methods as follows:

- Check that the results from hematocrit controls for both i-STAT and comparative methods are acceptable.
- If i-STAT hematocrit results obtained using the "K_3EDTA" setting are consistently lower than those on the comparative method, the "K_2EDTA" setting may be a better choice. If agreement is better after multiplying the "K_3EDTA"-customized i-STAT results by 1.0425, the customization setting should be switched to "K_2EDTA".
- Conversely, if i-STAT hematocrit results obtained using the "K_2EDTA" setting are consistently higher than those on the comparative analyzer, the "K_3EDTA" setting may be a better choice. If agreement is better after dividing the "K_2EDTA"-customized i-STAT results by 1.0425, the customization setting should be switched to "K_3EDTA".
- If an unacceptable system bias still exists, contact i-STAT Technical Support at 1-800-366-8020, option 1.

HEMATOLOGY ANALYZERS AND K_2EDTA AND K_3EDTA SAMPLE COLLECTION TUBES

Hematocrit results on hematology analyzers from samples collected in K_3EDTA and K_2EDTA tubes will be equivalent. This is because the osmotically-balanced diluent reverses the red blood cell shrinkage caused by the anticoagulant.[5] It should be clear that results from K_2EDTA and K_3EDTA tubes will be equivalent, but lower, on an analyzer calibrated to MH-K_3EDTA than on an analyzer calibrated to MH-K_2EDTA.

i-STAT has become aware that some customers have selected their i-STAT hematocrit customization according to the type of EDTA anticoagulant in the collection tube used for samples for the hematology analyzer. As explained above, the selection of the "K_2EDTA" or the "K_3EDTA" customization for i-STAT analyzers is based upon the microhematocrit method (MH-K_2EDTA or MH-K_3EDTA) to which the hematology analyzer is calibrated, rather than on the collection tube used for the hematology analyzer.

EXPECTED LEVEL OF METHOD AGREEMENT

Average i-STAT hematocrit results over a group of samples should normally agree with those from the comparative method within ± 2 %PCV at 29 %PCV and below, ± 3 %PCV from 30 to 50 %PCV, and within 10% above 50 %PCV when the following conditions are met:

- i-STAT analyzers are customized correctly.
- Comparative analyzer is calibrated correctly.
- Sample handling is optimal for both i-STAT and comparative methods.
- Samples are unaffected by factors listed in the i-STAT Cartridge and Test Information sheet for Hematocrit or in the user documentation for the comparative method.

Note: The original agreement criteria recommended by i-STAT for the calibration verification procedure (using the microhematocrit method) was 3 %PCV across the entire measurement range. i-STAT believes that these new criteria are more clinically relevant and should be applied to method comparisons and the calibration verification procedure.

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Calibration Verification and the i-STAT System

INTRODUCTION

Calibration Verification is a procedure performed to confirm that the calibration of an instrument or test system has remained stable throughout the reportable range. In many countries, this procedure is called a linearity check. Because of the inherent stability of the i-STAT System, Abbott Point of Care Inc. does not make any specific recommendations for the calibration verification procedure. Therefore, it is the responsibility of the laboratory to determine when and how this procedure should be performed. The information presented below is intended to help the laboratory make this determination.

In the United States, laboratory regulations (CLIA) require that for tests categorized as Non-Waived, a calibration verification procedure be performed and documented at least once every six months. The information presented below supports Abbott Point of Care Inc's. position that it is the cartridges, or more specifically, the sensors, rather than the analyzers that should be subject to the six-month check on the accuracy of the reportable range, and supports Abbott Point of Care Inc's. claim that all analyzers that pass the Electronic Simulator test are equivalent, which should preclude the testing of three levels, twice a year, on each and every analyzer on site.

In addition to the six-month time frame for a calibration verification procedure for Non-Waived tests, CLIA and laboratory accrediting bodies in the US list the following as possible reasons to perform calibration verification:

- validate the reportable range of a test before the test system is put into use.
- verify that a change in reagent lot numbers does not affect either the reportable range or control values.
- troubleshoot when control values are out-of-range.
- verify that results have not been affected by maintenance or repair procedures.

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STABILITY OF CALIBRATION IN THE i-STAT SYSTEM

The i-STAT System is a unit-use testing system. Components that cause shifts and drifts in results in multi-use analyzers: sensors (electrodes), calibration solution, fluid-handling channels and pumps, are housed in a disposable test cartridge. The sensors are exposed to sample only once, so there is no protein build-up which is a major cause for deterioration of sensor slope and the need to calibrate and/or verify calibration on a frequent basis in multi-use analyzers.

The stability and consistency of the manufacturing process allow the slope of the sensors to be programmed into the analyzer's software. A one-point calibration to set the intercept accounts for any day-to-day variation in testing conditions. When stored according to directions, the cartridges are stable up to the expiration date.

The analyzer houses the mechanical and electrical systems necessary to control fluid movement within the cartridge, control the temperature when measurements are performed at 37°C, measure barometric pressure, measure electrical signals generated by the sensors and display and transmit results. The analyzer's functions are factory calibrated to specifications that are programmed into the analyzer along with acceptability limits, which when exceeded cause the analyzer to display quality check messages or to display *** rather than results.

The accuracy of results and dependability of the internal quality check system depend upon the ability of the analyzer to take accurate and sensitive signal readings from the sensors. To check this function, i-STAT developed an electronic control device. The Electronic Simulator simulates two levels of electronic signals that stress the analyzer's signal detection function both below and above the reportable ranges. Injecting signals directly into the analyzer allows very tight control limits to be set. Control limits for liquid controls are set wide enough to allow for sensor-to-sensor variation. All analyzers that pass the Electronic Simulator test are equivalent and any variations in results are caused by within and between lot variations in the cartridges.

The combination of unit-use cartridges, inherently stable electronics of the analyzer, and reliability of the Electronic Simulator check provides the stability needed for a point-of-care testing system and reduces the need for frequent stability or calibration verification checks.

VALIDATING THE REPORTABLE RANGE

The accuracy of results over the entire reportable range could be assessed by testing the same patient samples on the new system and on a system with known accuracy and comparing results using an acceptable difference criteria. However, it is difficult to find samples that cover the low and high ends of the reportable ranges of many analytes. Ideally, the samples used to validate the ranges should have the same matrix as the patient samples. Tonometered blood can be used to validate the ranges for $\boldsymbol{P}\mathrm{CO}_2$ and $\boldsymbol{P}\mathrm{O}_2$. But for most analytes, there are no whole blood samples commercially available for this purpose.

Although the i-STAT Calibration Verification Set is aqueous-based, the target values have been determined over many lots of cartridges and results on these solutions when compared to the target values should indicate the performance of a particular lot of cartridges.

ASSESSING LOT-TO-LOT VARIATION

Lot-to-lot variation over the entire reportable range for any reagent system could be assessed by testing calibration verification solutions on old and new lots in parallel. This procedure should be suspended once it has been determined that lot-to-lot variation is acceptable. Quality controls samples with concentrations at decision points should always be used to assess new lots or reagent before results are reported.

Because the manufacturing process for the cartridges produces consistent lots with little lot-to-lot variation, Abbott Point of Care Inc. does not make any recommendations for this procedure. Each new lot of cartridges should be assessed using the i-STAT quality control solutions according to the procedure in the System Manual.

TROUBLESHOOTING

Should quality control sample results fall outside of the acceptable ranges, calibration verification samples with very low or very high concentrations could be helpful in characterizing a reagent problem. This information would be most valuable if the user could affect a change in the calibration of the test system to correct the problem.

The i-STAT System was designed so that the intended users, who are not familiar with laboratory procedures, cannot make any adjustments that would affect results. The characteristics of the sensors are well known and results of control solutions would be sufficient for Technical Support specialists to help users resolve control out-of-range problems.

VERIFYING THAT RESULTS HAVE NOT BEEN AFFECTED BY MAINTENANCE OR REPAIR PROCEDURES

In multi-use systems, reagents and samples are run through the analyzer and, therefore, there should be a method of checking that all components are performing together according to specifications after any one component is affected. Calibration verification solutions can be used to verify that the calibration or slope of the measuring system has not been affected by the maintenance or repair procedure.

The user cannot perform any maintenance procedures on the i-STAT System. However, the software in the analyzer is updated periodically – a procedure that potentially could cause a change in results. In fact, software updates are released to ensure that results do not change over time. Calibration verification solutions could be tested to verify that results have not been affected. This procedures should be suspended or replaced with controls once it has been determined that software updates do not affect results. Since i-STAT has been effectively updating software for over 10 years, this procedure is not part of Abbott Point of Care Inc's. recommended quality program.

Repaired and newly purchased analyzers are received with factory calibration. Again, the Electronic Simulator can better assure that the analyzer's most important function is within factory specifications than calibration verification or control solutions.

Testing calibration verification samples or comparing patient sample results on a new or repaired analyzer with an older analyzer will assess cartridge performance only. Any variations in analyzer performance will not be statistically discernable above the performance of the cartridges. When multiple analyzers are to be used at a facility, Abbott Point of Care Inc. recommends including at least two analyzers in any performance verification studies so that statistics reflect the "system."

CALIBRATION VERIFICATION LEVEL RECOMMENDATIONS

Product Title	Applicable Cartridges	Analytes	Which Levels should be run to verify the reportable range?
i-STAT Calibration Verification Set	G, Crea, E3+, EC4+, 6+, EC8+, G3+, EG6+, EG7+, CG4+, and CG8+	Sodium Potassium Chloride Ionized Calcium pH PCO_2 PO_2 Glucose Lactate BUN/Urea Creatinine	1, 3, and 5
i-STAT CHEM8+ Calibration Verification Set	CHEM8+	Sodium Potassium Chloride TCO_2 Ionized Calcium Glucose BUN/Urea Creatinine	1, 3, and 5 Note: i-STAT CHEM8+ Level 1B Control is available for purchase for customers who want to test lower levels of TCO_2 than that contained in the Level 1 Calibration Verification solution.
i-STAT Cardiac Marker Calibration Verification Set.	cTnI	cTnI	1, 2, and 3
RNA Medical® Hematocrit Calibration Verification Controls	E3+, EC4+, 6+, EC8+, EG6+, EG7+, CG8+, and CHEM8+	Hematocrit	1, 3, and 5
i-STAT BNP Calibration Verification Controls	BNP	BNP	1, 2, and 3

When performing the calibration verification procedure to meet a six-month calibration verification requirement, include each sensor and a representative selection of analyzers.

NOTES:

Calibration Verification or a linearity check for hematocrit can also be performed by a manual method using blood collected in lithium heparin tubes and manipulated to create three levels of hematocrit. Target values for Hematocrit for this manual method can be obtained from the bench top lab analyzer.

The upper limit of the reportable range for PO_2 is 800 mmHg. The highest PO_2 level in the i-STAT Calibration Verification set is just over 450 mmHg. Oxygen levels above 450 mmHg are so unstable in aqueous solutions that it would be impossible to make reliable measurements above 450 mmHg. Whole blood samples can be tonometered with 100% oxygen to create a sample around 700 mmHg at sea level.

REFERENCE

Code of Federal Regulations, 42CFR493, Subpart K – Quality System For Non-Waived Testing, §493.1255 – Standard: Calibration And Calibration Verification Procedures. (January 24, 2003)

i-STAT®
TECHNICAL BULLETIN

ACT Test Result Calibration Options: PREWARMED vs. NON-PREWARMED Result Calibration Modes for the i-STAT®1 Analyzer

BACKGROUND

The Activated Clotting Time (ACT) test has been in existence for over 30 years. It is the most popular test for measuring the effect of heparin administered during an interventional procedure. By placing an activator in the test chamber, the blood sample is "activated" to promote clotting. When heparin is present in the sample, the clotting is delayed in proportion to the amount of "anticlotting" effect of the heparin.

Since its inception, numerous changes have taken place to ACT tests, including increased automation and decreased sample volume. Today, there are many new, fully automated, low blood volume ACT tests on the market, in addition to the older, macro blood volume, semi-automated tube-based systems (*i.e.*, Hemochron®, Actalyke™). The micro sample ACT systems typically employ test cartridges or cards (instead of tubes), and all have incorporated an automatic test cycle prewarming step that brings the ACT testing chamber to 37°C prior to initiating the clotting reaction. As blood clotting is an enzymatic process, the temperature at which the clotting cycle takes place has a marked impact on the rate at which the blood clot forms. The ACT tests that incorporate a prewarming step allow the entire clotting reaction to take place at 37°C. ACT tests that do not use a prewarming step are subject to a delay before the blood specimen reaches (and stabilizes at) 37° degrees; the actual time needed to reach 37°C is dependant on the starting temperature of the sample test tube. For example, a 30°C blood sample placed into a (non-prewarmed) 25°C ACT tube will take a few minutes before the test environment (blood, reagent, tube) stabilizes at 37°C. The result of this thermal delay is an increase in the reported ACT clot time that will depend on sample tube temperature.

ACT Instruments WITH an automatic prewarming step	**ACT Instruments WITHOUT an automatic prewarming step**
Medtronic® ACTII (plus)	Hemochron 801/401/8000/Response
Medtronic HMS (plus)	Actalyke
Bayer/TAS HMT	
Roche ACT	
Hemochron® Jr. (Signature/PCL)	
i-STAT	

Abbott
Point of Care

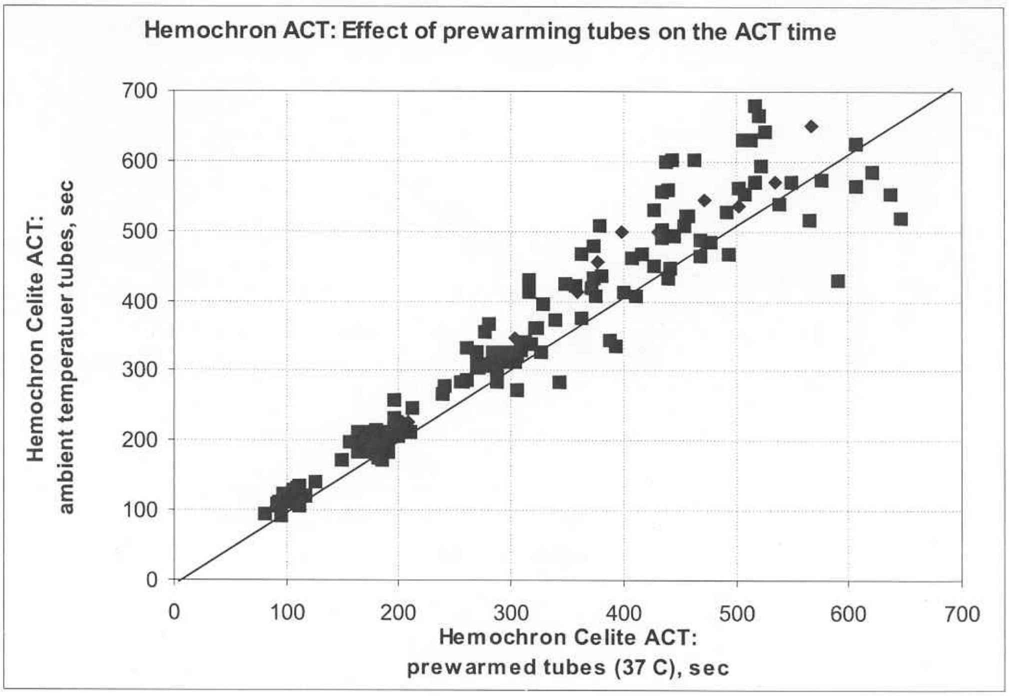
i-STAT ACT CALIBRATION

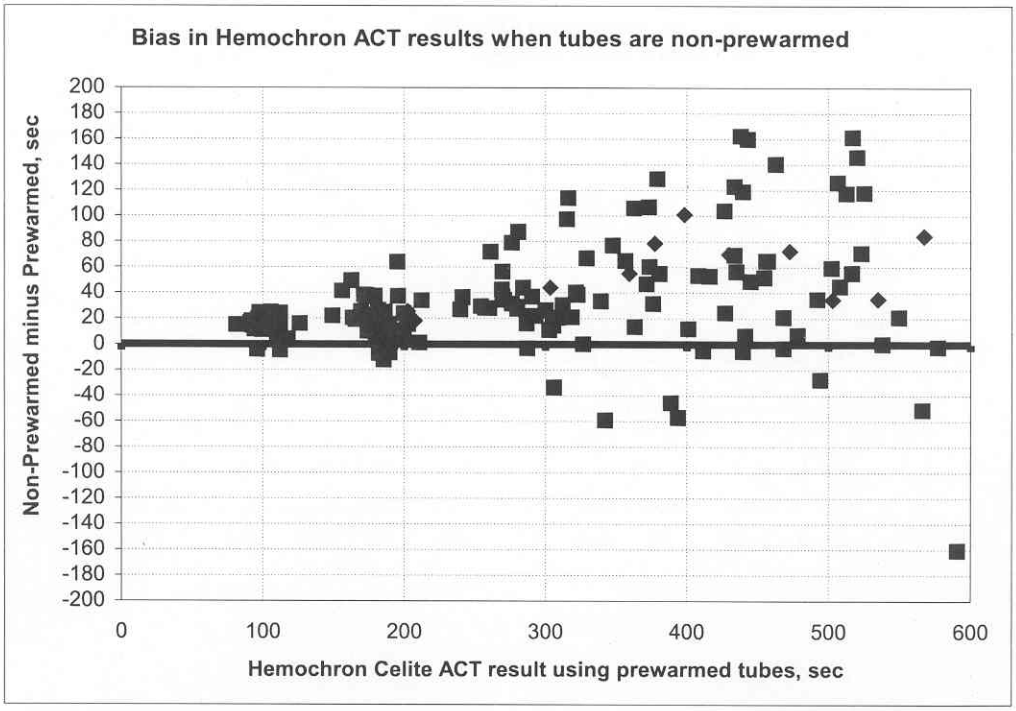
Currently, the i-STAT® Celite® ACT and i-STAT® Kaolin ACT tests are factory calibrated by mathematically adjusting the raw i-STAT "clot time" to match the Hemochron® Celite tube result. This calibration is performed by testing cartridges and Hemochron Celite tubes side by side, using a range of heparinized, non-hemodiluted whole blood samples, and using **Hemochron tubes prewarmed to 37°C.**

Customers who are familiar with macro-sample ACT methods like Hemochron and Actalyke™, and who do not preheat their tubes prior to each test, have found that the bias in results between their previous ACT method and the i-STAT ACT may require changing familiar clotting time target values. In order to ease the changeover to the i-STAT ACT method under these circumstances, i-STAT now provides a choice between the current 37°C result calibration and a new "non-prewarm" (or ambient temperature) result calibration. The additional calibration mode allows an i-STAT ACT cartridge to deliver results that will be a closer match for those users who are familiar with macro-sample methods without automatic prewarming cycles, and should reduce the need to make large changes to ACT target times or ranges. Since micro-sample methods (Medtronic HR-ACT, Hemochron Jr. ACT+) already incorporate preheating of the test cuvettes, users with ACT target times and ranges based on these methods should continue to use their current i-STAT 37°C calibration.

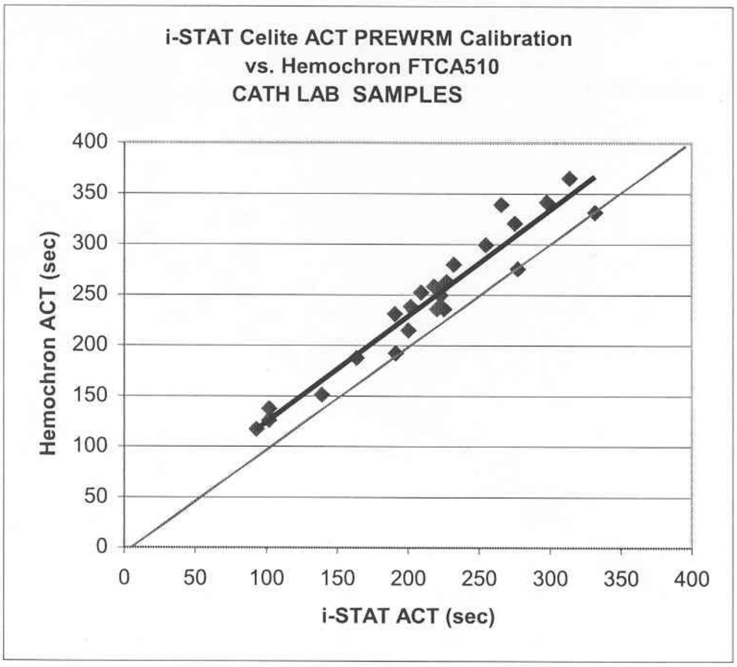
REPRESENTATIVE DATA

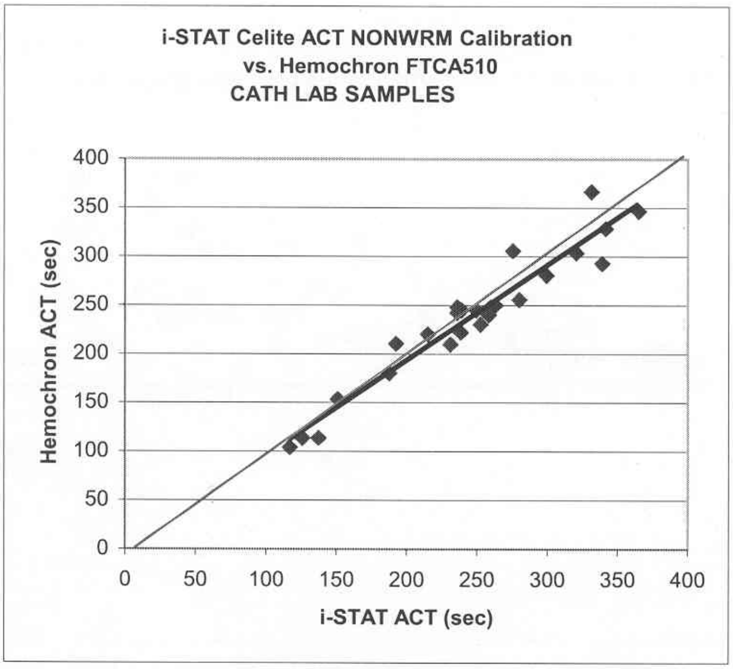
Effect of Sample Tube Temperature on Hemochron ACT Results using Paired Samples: Prewarmed sample tubes vs. Non-prewarmed sample tubes.





i-STAT Celite ACT vs. Room Temperature Hemochron FTCA510: Prewarmed **(PREWRM)** vs. Non-prewarmed **(NONWRM)** calibration modes.

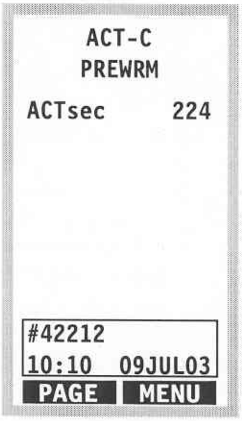


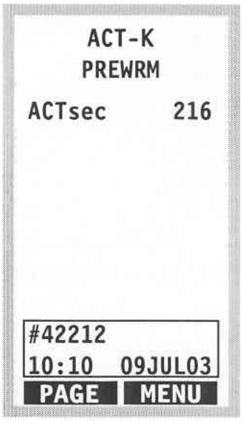


ANALYZER DISPLAY AND CDS CHANGES

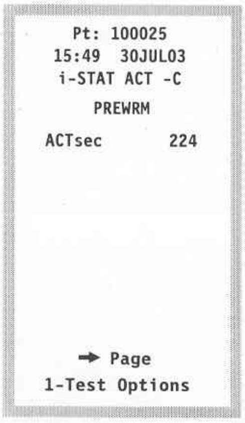
Due to the new ACT result calibration option, there are several changes to the analyzer display as well as to the Central Data Station (CDS). Major changes are noted below:

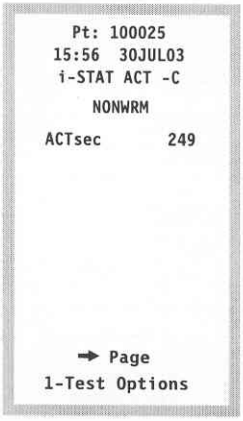
- The i-STAT PCA and BAM are NOT capable of offering the new ACT result calibration option. All PCA and BAM ACT results continue to use the original ACT calibration (PREWRM). To clearly identify this calibration, ACT results reported on the i-STAT PCA will show PREWRM on the result screen.

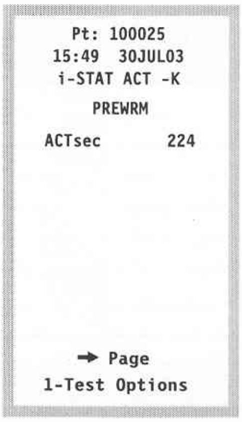

ACT-C
PREWRM
ACTsec 224
#42212
10:10 09JUL03

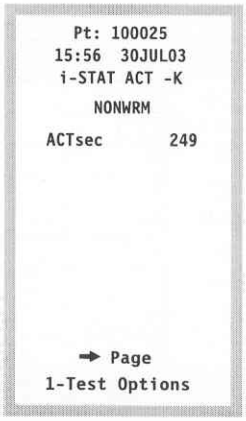

ACT-K
PREWRM
ACTsec 216
#42212
10:10 09JUL03

- The ACT test results that will be displayed on the i-STAT 1 analyzer now show the calibration setting that was used to perform the ACT calculations.

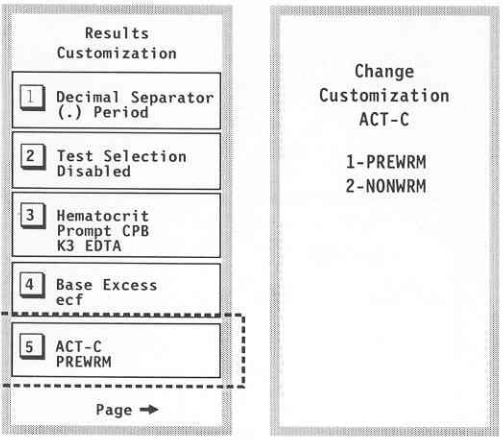

Pt: 100025
15:49 30JUL03
i-STAT ACT -C
PREWRM
ACTsec 224


Pt: 100025
15:56 30JUL03
i-STAT ACT -C
NONWRM
ACTsec 249


Pt: 100025
15:49 30JUL03
i-STAT ACT -K
PREWRM
ACTsec 224


Pt: 100025
15:56 30JUL03
i-STAT ACT -K
NONWRM
ACTsec 249

- The i-STAT 1 analyzer is capable of offering both the **NONWRM** and **PREWRM** ACT customization settings. These customizations can be viewed, selected and changed via the RESULTS CUSTOMIZATION section on the i-STAT 1 analyzer



Results Customization

1 Decimal Separator (.) Period

2 Test Selection Disabled

3 Hematocrit Prompt CPB K3 EDTA

4 Base Excess ecf

5 ACT-C PREWRM

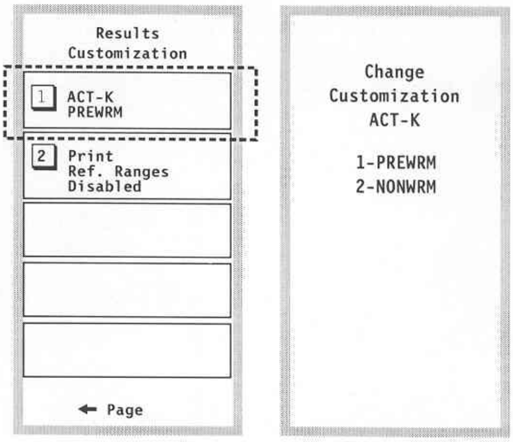
Page →

Change Customization ACT-C

1-PREWRM

2-NONWRM

Celite ACT handheld customization.



Results Customization

1 ACT-K PREWRM

2 Print Ref. Ranges Disabled

← Page

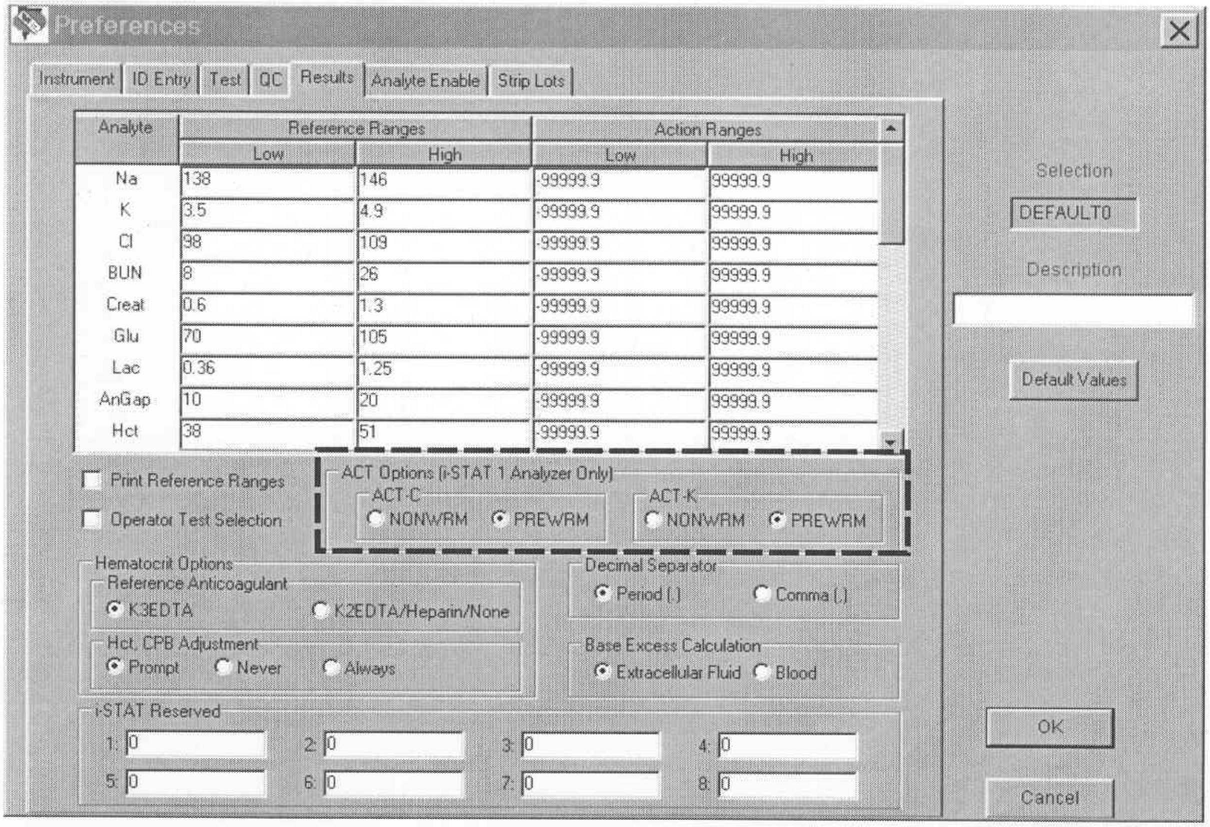
Change Customization ACT-K

1-PREWRM

2-NONWRM

Kaolin ACT handheld customization.

- For i-STAT 1 analyzers used in conjunction with CDS version 5, the new ACT customization options are located on the RESULTS tab of the Preferences section of the individual customization profile (see highlight). Users should select the desired calibration mode for each i-STAT ACT type (Celite and/or kaolin).



Analyte	Reference Ranges		Action Ranges	
	Low	High	Low	High
Na	138	146	-99999.9	99999.9
K	3.5	4.9	-99999.9	99999.9
Cl	98	109	-99999.9	99999.9
BUN	8	26	-99999.9	99999.9
Creat	0.6	1.3	-99999.9	99999.9
Glu	70	105	-99999.9	99999.9
Lac	0.36	1.25	-99999.9	99999.9
AnGap	10	20	-99999.9	99999.9
Hct	38	51	-99999.9	99999.9

☐ Print Reference Ranges

☐ Operator Test Selection

ACT Options (i-STAT 1 Analyzer Only)

ACT-C: ○ NONWRM ● PREWRM

ACT-K: ○ NONWRM ● PREWRM

Hematocrit Options

Reference Anticoagulant: ● K3EDTA ○ K2EDTA/Heparin/None

Hct, CPB Adjustment: ● Prompt ○ Never ○ Always

Decimal Separator: ● Period (.) ○ Comma (,)

Base Excess Calculation: ● Extracellular Fluid ○ Blood

i-STAT Reserved

1: 0 2: 0 3: 0 4: 0

5: 0 6: 0 7: 0 8: 0

Selection: DEFAULT0

Description:

LIMITATIONS AND WARNINGS

- The NONWRM calibration mode applies to the Patient Path only, and will not be applied to the Control or Proficiency Testing pathway. *Control or Proficiency samples run in the Patient Pathway may produce erroneous results.*
- Different locations within a given hospital may utilize different calibration modes/customization profiles. Prior to testing patient samples, ensure the appropriate calibration mode is employed.

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i-STAT®
TECHNICAL BULLETIN

Support Services

Abbott Point of Care Inc. and its distributors are committed to helping you resolve any problems with the i-STAT System: Portable Clinical Analyzer, i-STAT 1 Analyzer, cartridges, accessories and Central Data Station software. For technical assistance within the United States, please call Technical Services at 800-366-8020 toll free. Outside the U.S., please contact your local i-STAT distributor.

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DOCUMENTATION AND SOFTWARE UPDATE FOR THE i-STAT SYSTEM: APRIL 2008

In addition to important updates to documentation about the i-STAT® System, this package contains the necessary items to perform the required software upgrades on your i-STAT System. Items enclosed are detailed in the table below. Please follow instructions carefully. Thank you for your prompt attention in performing this upgrade.

Contact i-STAT Technical Support at 1-800-366-8020, option 1, if you have any questions or need further assistance.

		SENT TO			
DOCUMENTATION UPDATES		all users	i-STAT 1 users only	CDS Version 5 Users	i-STAT/DE Users
ITEM	**COMMENT**				
Add/Delete sheet, i-STAT 1 System Manual	Lists which sections should be replaced with updated sections.		X		
Add/Delete sheet, i-STAT System Manual	Lists which sections should be replaced with updated sections.	X			
Cartridge and Test Information Sheet for Creatinine	New or revised information that should be retained.	X			
Cartridge and Test Information Sheet for Total Carbon Dioxide / TCO_2	New or revised information that should be retained.	X			
i-STAT 1 System Manual Section 6: i-STAT 1 Downloader	New or revised information that should be retained.		X		
i-STAT 1 System Manual Section 21: Downloader Programming and Wiring	New or revised information that should be retained.		X		
Technical Bulletin: Analyzer Coded Messages	New or revised information that should be retained.	X			
Technical Bulletin: Proficiency Testing on the i-STAT System	New or revised information that should be retained.	X			
Technical Bulletin: The i-STAT System and Waived Status	New or revised information that should be retained.		X		
Technical Bulletin: April 2008 Update to the i-STAT Central Data Station Version 5	New or revised information that should be retained.			X	
i-STAT/DE Customer Letter	New or revised information that should be retained.				X

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SOFTWARE UPDATES

DOCUMENT	COMMENT	all users	i-STAT 1 users only	CDS Version 5 Users	i-STAT/DE Users
Control and Calibration Verification Value Assignment Sheet Notice	Directs customer to www.abbottpointofcare.com for printing new Value Assignment sheets.	X			
Product Update: JAMS057 / JAMS124 / HPCA057	Describes changes in new software and summarizes updates to documentation.	X			
CD-ROM and/or Floppy Disk: i-STAT Software for Analyzers	Each disk contains all versions of software.	X			
CD-ROM: Central Data Station Version 5.22	The Quality Check Code Viewer contains a new feature.			X	
Technical Bulletin: Updating Analyzer Software	For use in updating software using a computer with Windows 95 or higher. These instructions must be used for updating i-STAT 1 Analyzers.	X			
Technical Bulletin: Instructions for Updating Software: Jammit Utility	For use in updating software from a computer with Windows 3.1.	X			
Technical Bulletin: Updating Analyzer Software for i-STAT/DE Users	Document describes specific instructions for updating analyzer software when using i-STAT/DE.				X
Confirmation Postcard	Complete and return to i-STAT after upgrade has been performed.	X			

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i-STAT®
PRODUCT UPDATE

SOFTWARE AND CARTRIDGE TEST INFORMATION
UPDATE: APRIL 2008

This update includes new software for the i-STAT 1 Analyzer, i-STAT Portable Clinical Analyzer and Philips Medical Systems Blood Analysis Module. The appropriate materials required for your institution to perform the update are included.

This is a mandatory update. If you did not receive a disk or CD-ROM with the correct software for your analyzers (see list below), please call to request one. In the US, call i-STAT Technical Support at 800-366-8020, option 1. Outside the US, please contact your local support representative.

ANALYZERS

The correct version of software and CLEW to install in your analyzers is listed below.

STANDARD SOFTWARE		
i-STAT Portable Clinical Analyzer	**i-STAT 1 Analyzer**	**Blood Analysis Module**
JAMS057 & CLEW A15	JAMS124 & CLEW A15	HPCA057 & CLEW H15
Japan: JAMS057 & CLEW C15	Japan: JAMS124 & CLEW A15	Japan: HPCA057 & CLEW J15

Expiration Date

Please note that the current software expires 18 June 2008.

Fifteen days before the software expires, a message will be displayed to alert the user of the pending expiration date. If this update is not performed by 18 June 2008, the analyzer and Blood Analysis Modules will display "INVALID OR EXPIRED CLEW – SEE MANUAL" (quality check code 12).

The new software expires 17 December 2008.

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i-STAT 1 System Manual

The i-STAT 1 Downloader and the i-STAT 1 Downloader Programming and Wiring sections of the i-STAT 1 System Manual contain two new caution statements:

- Only the i-STAT provided printers may be connected to the Downloader printer port.
- An ethernet cable and serial (DB9) cable may NOT be connected to the Downloader at the same time.

The i-STAT 1 Downloader section also contains two additional new caution statements:

- The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).
- Users should not connect the Downloader or the Downloader/ Recharger to a medical electrical system.

CENTRAL DATA STATION

Central Data Station Version 4

There is no update to CDS Version 4.

Central Data Station Version 5

Update your CDS Version 5 application to Version 5.22 by using the CD-ROM included in this software update packet. **This is a mandatory update.**

This update includes:

- A new column in the Quality Check Code viewer indicating the Quality Code Category corresponding to the individual quality check code.

See the enclosed Technical Bulletin entitled "April 2008 Update to the Central Data Station Version 5" for full details.

i-STAT/DE

Update your i-STAT/DE application to Version 1.10 using the CD-ROM included in this software update packet. **This is a mandatory update**.

In addition to minor improvements to user interface flow, i-STAT/DE Version 1.10 includes performance enhancements required to maintain compatibility with current cartridges and analyzers.

Please see the enclosed i-STAT/DE Customer Letter for full details.

STANDARDIZATION

CLEW Update

The i-STAT System is designed to eliminate operator influence on delivered results. With the exception of the immunoassay cartridges, the user is not required to enter lot-specific calibration information into the instrument. The micro-fabricated sensor technology produces very repeatable devices from lot to lot which allow the Analyzers to use the same set of standardizing values for extended periods of time.

Nevertheless, continuous manufacturing process improvements made by i-STAT necessitate re-establishing standardization values from time to time to maintain long-term consistency. This is equivalent to adjusting calibration on a traditional analyzer. It has been our practice to accomplish this with periodic releases of software. This new CLEW re-establishes the standardization and incorporates refinements to the internal quality monitoring system.

Future shipments of cartridges may require the installation of this software prior to the use of the cartridges. Failure to update prior to using these cartridges will result in quality check code 69, "CARTRIDGE TYPE NOT RECOGNIZED".

This software supports all current non-expired cartridges.

CARTRIDGE AND TEST INFORMATION SHEETS

Updated Creatinine and TCO_2 CTI sheets are enclosed. Both contain updated Precision Data, while the Creatinine sheet also contains updated Reference information.

TECHNICAL BULLETINS

Three revised Technical Bulletins are included in this update packet.

The "Analyzer Coded Message" Technical Bulletin now includes:

- Updated troubleshooting recommendations for code 86 on page 6. For i-STAT Analyzers exhibiting Code 86 when stored in a Downloader/ Recharger, users are now directed to move the Downloader/Recharger to an open location free of obstructions and external heat sources such as heater vents or other electronic equipment.
- Additional information regarding the potential cause(s) of code 126 on page 8.

The "Proficiency Testing" Technical Bulletin now includes:

- Updated information on pages 1-2 regarding Proficiency Testing for Non-Waived tests vs Waived tests.
- An updated chart listing which cartridges are thermal vs. non-thermal on page 3.
- Changes and additions to the Proficiency Testing Survey Providers table.

The "i-STAT System and Waived Status" Technical Bulletin contains current regulatory requirements for waived testing and updated recommendations for the monitoring of room temperature and refrigerated storage for customers using the CHEM8+ cartridge as waived.

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TECHNICAL BULLETIN

UPDATING ANALYZER SOFTWARE

OVERVIEW

This Technical Bulletin is specially designed to guide users through the process of updating analyzer software in both the i-STAT 1 and the Portable Clinical Analyzer. The following table describes the procedures that can be used to update the different analyzer types, and on what page in this Technical Bulletin those procedures can be found.

Analyzer Type	Utility For Updating Analyzer Software and Page Location in Technical Bulletin
i-STAT 1 Analyzer	1. Customization Workspace: page 8. 2. JAMMLITE Utility: page 1 3. Analyzer-to-Analyzer Update: page 8 (Note: this procedure can be used to update subsequent analyzers only after one i-STAT 1 Analyzer has been updated using utility 1 or 2 above).
i-STAT Portable Clinical Analyzer	1. JAMMLITE Utility: page 1 2. Analyzer-to-Analyzer Update: page 8 (Note: this procedure can be used to update subsequent analyzers only after one Portable Clinical Analyzer has been updated using the JAMMLITE utility).

JAMMLITE UTILITY

The JammLite Utility must be used to update software in the i-STAT®1 Analyzer and can be used to update the i-STAT Portable Clinical Analyzer and the Blood Analysis Module. The JammLite procedure is simple with just one screen for all analyzer types and software versions.

To use this utility, you must have a computer with Windows® 95 or higher. An i-STAT Central Data Station Version 5 or a Point of Care Central Workstation meet this requirement and can be used.

If this is the first time you are updating your analyzer, follow the Detailed Procedure. If you just need reminders, follow the Summary of the Procedure.

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SUMMARY OF THE JAMMLITE PROCEDURE

How to	Step	Page
Check battery voltage Save the data on Portable Clinical Analyzers	1	2
Disable Customization on the Central Data Station	2	2
Shut down all programs on the computer	3	3
Connect an IR Link or Downloader* to the computer	4	3
Access the C:\> prompt	5	4
Transfer the files from the JAMS disk to the computer	6	5
Access the JammLite Utility	7	5
Select the instrument (analyzer) type to be updated	7	5
Select the local port or select TCP/IP and enter the IP address	7	5
Select the Application software and CLEW	7	6
Click on Update and follow the directions on the screen	7	6
DO NOT move analyzer during update	7	6
Click on Close	7	6
Click on Exit or X in upper right corner of screen	7	6
Re-start the CDS, update CLEW, re-eanable Customization	8	6
Insert an Electronic Simulator into each updated analyzer	9	7

* It is not neccessary to connect a serial Downloader if using network protocol to update i-STAT 1 Analyzer.

DETAILED JAMMLITE PROCEDURE

Step (1)

Save Stored Results & Check Battery Voltage

__Save Data:__ All test records are erased in the i-STAT Portable Clinical Analyzer (series 200) when the application software is updated. Download each analyzer to the Central Data Station (CDS) program or ensure that all test records have been transcribed before updating a Portable Clinical Analyzer. Test records are not erased from the i-STAT1 Analyzer (series 300).

- There are two types of software in the analyzers: application (JAMS) and CLEW.
- The Product Update lists the software that is to be updated.
- Test records will not be erased if only the CLEW software is updated.

Check Battery Voltage: Analyzers consume power during the software update. For the software update, the battery voltage should be well above the 7.5 V point at which the low battery message is displayed.

Step (2)

Disable Customization on CDS

If you do not use Customization or Customization is disabled, skip this step. If you use Central Data Station Version 5 and your CDS is on Version 5.18a or higher, skip this step.

If you are not sure if Customization is disabled, follow the steps below. The steps to disable customization differ for the Central Data Station Version 4 and Central Data Station Version 5. If you are not sure which CDS you have, click **Help** on the main menu bar, then click on **About....**

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on File on the menu bar.
4. Click on Disable Customization.
5. Click Yes to the confirmation messages and the Utility will close.

Central Data Station Version 5:

1. Click on Administration in the main menu bar.
2. Click on Customization.
3. Type in the Password. The default password is istat.
4. Click off the checkmark in the box beside Enable Customization at the top left of the window.

Step (3)

Shut Down All Programs

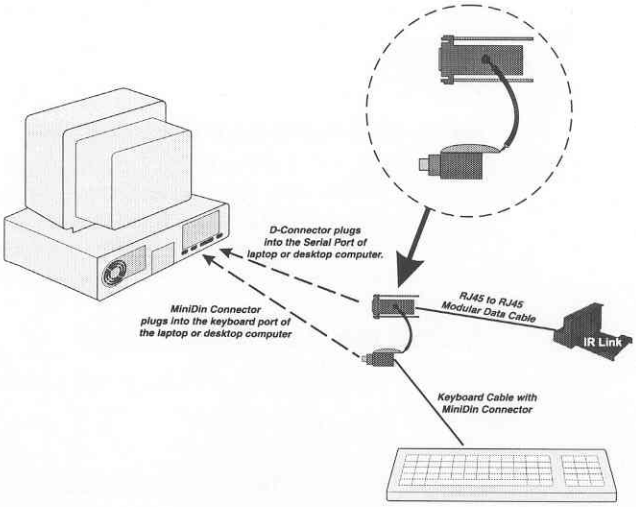
Exit the CDS and all other open programs.

Step (4)

Connect the IR Link and/or Downloader

IR Link connection:

- If using a Central Data Station Version 5, a Central Data Station Version 4 with digiboard, or any other computer using Windows 95 or above, connect the IR Link to a 9 pin COM port using an i-STAT Software Update Kit as illustrated below.


D-Connector plugs into the Serial Port of laptop or desktop computer.
MiniDin Connector plugs into the keyboard port of the laptop or desktop computer
RJ45 to RJ45 Modular Data Cable
IR Link
Keyboard Cable with MiniDin Connector

- If using a Central Data Station Version 4 with quad cards: Connect the IR Link to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors). COM5 is first port from the inside on the lower row.

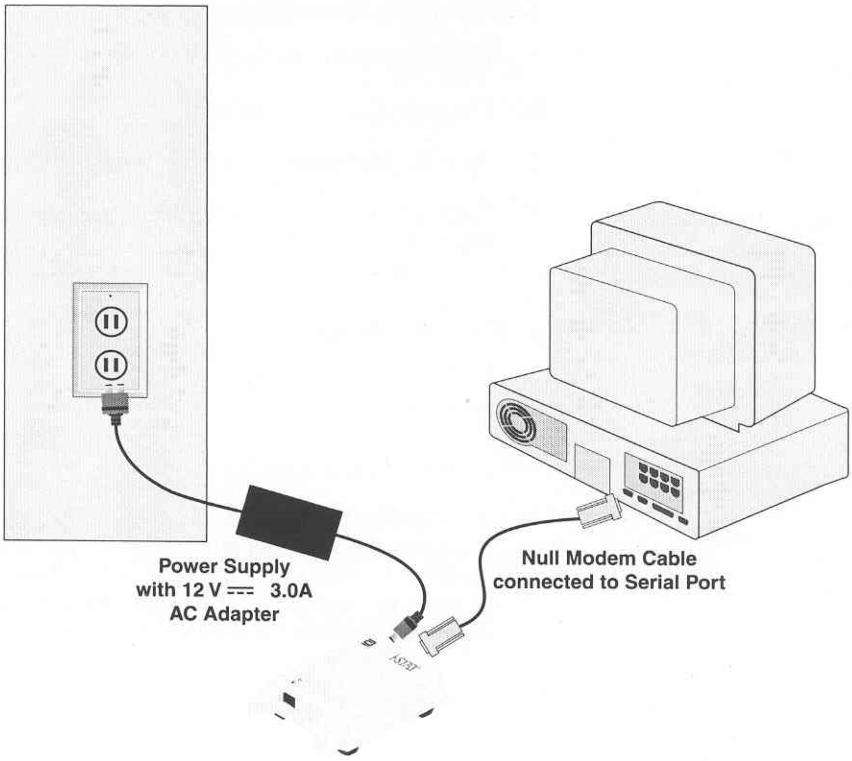
Blood Analysis Module connection:

- If using a Central Data Station Version 4, connect the BAM to COM5 on the back of the CDS using a Modular Data Cable (i-STAT grey flat cable with RJ45 connectors).
- If using a Central Data Station Version 5 or another computer, connect the BAM to a 9 pin COM port using the D-Connector and Mini Din Connector from an i-STAT Software Update Kit.

Note: Do not connect the BAM until instructed to do so by the JammLite program.

Serial Downloader connection:

- Connect a serial Downloader to a COM port using a DB9-DB9 Null Modem cable and plug the Downloader's power adapter into a wall outlet.



Network Downloader connection:

- Connect a network Downloader to the network using a network patch cable and plug the Downloader's power adapter into a wall outlet. The computer must also be connected to the network. The computer must support the TCP/IP network protocol.

Step (5)

Access the Command Prompt

- Click Start in the lower left corner of the window.
- Click Run.
- Type: **command** and press the Enter key.

Note: If you do not have access to the **Run** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

Step (6)

Transfer the Files

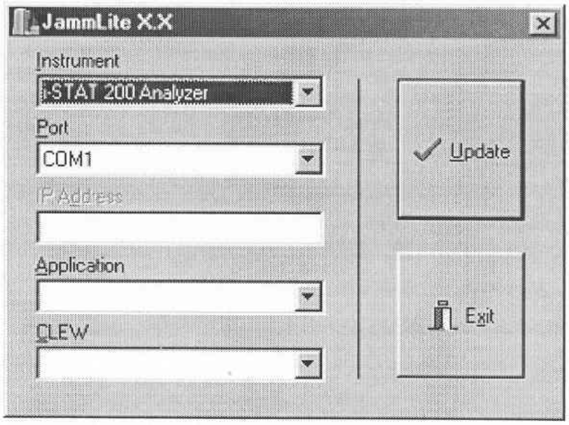
If using a JAMS/CLEW CD-ROM, place the CD-ROM into the CD drive. At the command prompt, **type x:transfer, where x is the letter corresponding to the CD-ROM drive on the computer being used to perform the update** and press the Enter key. (For example, if the CD-ROM drive on your computer is the D: drive, you would type **d:transfer** and press Enter.)

If using a JAMS/CLEW floppy disk, place the diskette in the A:drive. At the command prompt, type **A:transfer** and press the Enter key.

Step (7)

Using the JammLite Utility

1. At the C:\>bins prompt, type **jammlite** and press the Enter key. The following screen will be displayed with the new application and CLEW.


JammLite X.X
Instrument
Port
IP Address
Application
CLEW
Update
Exit

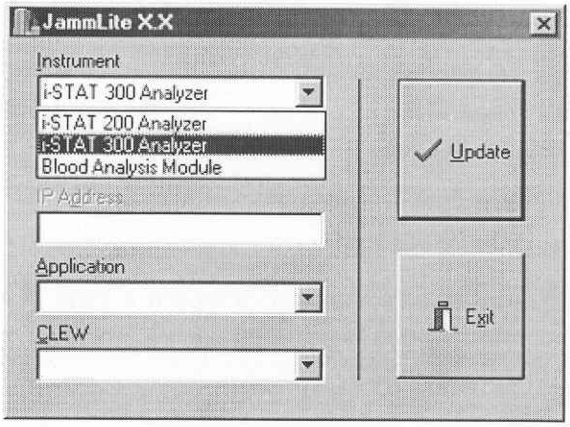
Instrument: i-STAT 200 Analyzer

Port: COM1

X.X is the current version of JammLite software.

---

2. Select the appropriate instrument from the Instrument drop-down list.


JammLite X.X
Instrument
i-STAT 200 Analyzer
i-STAT 300 Analyzer
Blood Analysis Module
IP Address
Application
CLEW
Update
Exit

Instrument: i-STAT 300 Analyzer

Note: i-STAT 200 Analyzer is the Portable Clinical Analyzer and the i-STAT 300 Analyzer is the i-STAT 1 Analyzer.

3. Select the port for the instrument being updated from the "Port" drop-down list. The JammLite program will list only available ports on the computer. For updates using a network Downloader, select TCP/IP. (The TCP/IP option is available only if i-STAT 300 is selected from the

"Instrument" drop down list.) Enter the IP address of the Downloader in the "IP Address" box.

4. Select the appropriate Application and CLEW from the Application and CLEW drop-down lists. Refer to the update package for the correct Application and CLEW. If the update is for CLEW only, select None for Application. Note that there are different application versions for the i-STAT 1 Analyzer, the Portable Clinical Analyzer and the Blood Analysis Module. JammLite will display all application software and CLEW appropriate for the selected instrument.
5. Click on the Update button to start the update. Appropriate instructions will be displayed. Follow the directions on the screen. The selected application and CLEW will be displayed on the Update Line.
6. During the update, do not move the analyzer or unplug the Blood Analysis Module until a screen is displayed indicating the update was successful.
7. Click on Close. The JammLite program will return to step 7 to allow any selections to be changed before starting another update.
8. When all analyzers have been updated, click on Exit or the X in the upper right corner of the DOS window.

Step (8)

Restarting the Central Data Station

If using a Central Data Station, re-start the software, update the Customization Profile(s) with the new CLEW and enable Customization if desired.

Central Data Station Version 4:

1. Click on the i-STAT Analyzer Customization Profile Utility icon or access by clicking Programs and i-STAT CDS.
2. Type in the Password. The default password is istat.
3. Click on Setup Mode.
4. Click on NEXT for the Language window.
5. Click on the new CLEW in the CLEW window and click on NEXT.
6. Click on NEXT in the Unit Set window.
7. Click on FINISH in the Preference window.
8. Click on FILE and Exit Program or click on the x in the upper right corner of the Utility window.
9. Click on the Central Data Station icon.

Central Data Station Version 5:

1. Click on the Central Data Station icon.
2. Click on Administration.
3. Click on Customization.
4. Type in the Password. The default password is istat.
5. Click the i-STAT Analyzer CLEW button.
6. Click the new version of CLEW and click OK.
7. If "Use Default Profile" is not check-marked beside any localization-based customization profiles, double click the box with the CLEW under the i-STAT Analyzer column (or Agilent BAM CLEW) and click the new version of CLEW.

8. Click a checkmark in the box beside Enable Customization at the top left of the window.
9. Click the x in the upper right corner of the Customization window to close it.

Step (9)

Verifying the Update

Run an external Electronic Simulator on updated analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

TROUBLESHOOTING

PROBLEM	RECOMMENDED ACTION
The Com port to be used for the update is not listed in the Port List	Exit the JammLite program and ensure that there are no other programs running which may be using the port (such as the Central Data Station). Restart the JammLite program to determine if the port is now listed.
A message appears on the screen that the port specified for the update could not be opened.	Verify that no other programs are using the port and that the correct port was selected.
A message appears on the screen that the specified application file could not be opened, has an error, or is not a valid application file.	Verify that all other programs are closed and that the proper application was selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the application update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that there was an error encountered during communication with the analyzer.	Ensure that the instrument is located properly in the IR Link or Downloader, and this it is not removed before the update is completed.
A message appears on the screen that the specified CLEW file could not be opened, has an error, or is not a valid CLEW file.	Ensure that all other programs are closed and that the correct CLEW is selected before re-attempting the update.
A message appears on the screen that the IR Link could not be configured to perform the CLEW update.	Verify that the IR Link is connected to the COM port, that the LED on the IR Link is red, and that the proper port is selected.
A message appears on the screen that the Downloader could not be configured to perform the update	Verify that the Downloader is connected to the COM port, the Downloader is powered, and that the proper port is selected.
A message appears on the screen indicating that nothing was selected for the update.	Select an Application and/or a CLEW prior to clicking on the Update button.

Quality Check Code 13 - Invalid or Expired CLEW after on-line customization is restored

If this quality check code occurs after successfully downloading new software and restoring on-line customization, the CLEW has not been updated to the new version in the Customization Profile. Update CLEW in the customization profile(s) and download the analyzers. The new CLEW will be installed in the analyzers.

Unsuccessful with Windows 95

Some computers with Windows 95 will not run JammLite. In this case, Jammit must be used to update analyzers. Before accessing the Jammit Utility, the computer must be rebooted.

ANALYZER-TO-ANALYZER SOFTWARE UPDATES

i-STAT 1 Analyzer

1 Any updated analyzer can be used as the sending analyzer. Select the Utility option under the Administration Menu on the sending analyzer. The Utility menu can be password protected. Enter the password or press the Enter key if no password has been specified. From the Utility Menu select **1-Send Software**. Select **1 – JAMS and CLEW** or **2-CLEW** as required for the update. The message "Waiting to Send" will be displayed.

2 Ensure that the receiving analyzer is off.

3 Place the sending and receiving analyzers facing each other on a flat surface about 30cm (1 foot) apart and align their IR windows. Move one analyzer toward the other until the message "Sending..." is displayed on the sending analyzer and a scrolling banner appears on the receiving analyzer.

4 Do not move the analyzers until the "Sending..." message is removed from the sending analyzer's display. The sending analyzer will return to the Send Software option and will display the result of the last software update as "Successful" or "Unsuccessful."

5 Select the Analyzer Status option under the Administration menu on the receiving analyzer and check that the new JAMS and/or CLEW are listed.

i-STAT Portable Clinical Analyzer

1 Any updated analyzer can be used as the Sending Analyzer. Run the external Electronic Simulator on the Sending Analyzer.

2 Transmit all data from the analyzer being updated (the Receiving Analyzer) to the Central Data Station. Data stored in the handheld analyzer will be lost after an application software update.

3 With the Simulator test results showing on the display of the Sending Analyzer, press and hold the DIS key and press the soft key for MENU. This displays the Utility Menu.

4 In the Utility Menu, select 3 - Send Software. The display will show the JAMS version and the CLEW in this analyzer. Verify that these are the appropriate versions. The analyzer screen will also say "Waiting to send".

5 Set both analyzers on a flat surface and align the Infrared Light-Emitting Diode (IR LED) windows so they directly face each other. (Refer to the analyzer picture on page 2-1 of the i-STAT System Manual for the location of the IR LED.)

6 On the Receiving Analyzer, make sure the display is off. Press and hold the * key and press the DIS key. The Sending Analyzer will begin sending software to the Receiving Analyzer. The display on the Sending Analyzer will change from "Waiting to send" to "Sending...", and a countdown bar will be displayed.

Note: Do not move the analyzers while the software is being sent.

7 When the display of the Sending Analyzer changes back to the Electronic Simulator result, the sending of software is complete. Do not press the DIS key on the Receiving Analyzer. Run the Electronic Simulator on the Receiving Analyzer.

8 To update software in another analyzer, repeat these instructions from Step 2.

PERFORMING A JAMS AND CLEW UPDATE ON AN i-STAT 1 ANALYZER USING THE CUSTOMIZATION WORKSPACE

1. ***Transfer the Files***

   - If using a JAMS/CLEW CD-ROM, place the CD-ROM into the CD drive. If using a JAMS/CLEW floppy disk, place the diskette in the A:drive.
   - Click **Start ⇨ Run...**
   - If using a CD-ROM, at the Open: prompt **type x:transfer, where x is the letter corresponding to the CD-ROM drive on the computer where the CDS application is installed** and press the Enter key. If using a JAMS/CLEW floppy disk, at the Open: prompt type **a:transfer** and press the Enter key.

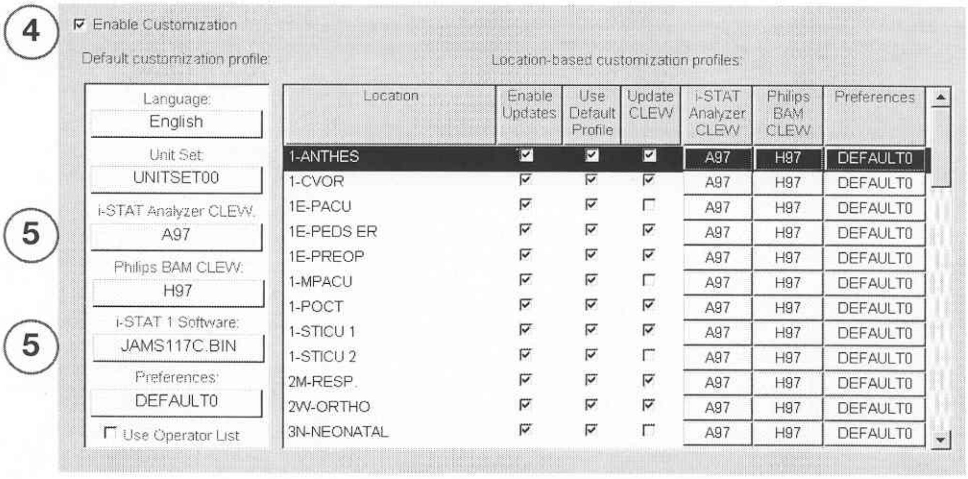
Note: If you do not have access to the **Run...** command, contact your Point-of-Care Coordinator or Information Technology (IT) department.

2. ***Start the Central Data Station Application (if not already open)***
   - Click on the Central Data Station icon.

3. ***Access the Customization Workspace***
   - Click on **Main ⇨ Open Administration Function ⇨ Customization**
   - Type in the Password. The default password is **istat**.

4. ***Enable Customization***
   - If the Enable Customization box is not already checked, click the box next to this listing.
   - Under the "Location-based customization profile:" section, make sure Enable Updates is checked for every location from which you wish to perform software updates on your i-STAT 1 Analyzers.

5. ***Select the Desired Analyzer CLEW and i-STAT 1 Software***
   - Under the "Default customization profile:" column, click on the i-STAT Analyzer CLEW button. Click the new version of CLEW and click OK.
   - Under the "Default Customization profile:" column, click on the i-STAT 1 Software button. Click the new i-STAT 1 software file and click OK.



☑ Enable Customization

Default customization profile:
Language: English
Unit Set: UNITSET00
i-STAT Analyzer CLEW: A97
Philips BAM CLEW: H97
i-STAT 1 Software: JAMS117C.BIN
Preferences: DEFAULT0
☐ Use Operator List

Location-based customization profiles:

Location	Enable Updates	Use Default Profile	Update CLEW	i-STAT Analyzer CLEW	Philips BAM CLEW	Preferences
1-ANTHES	☑	☑	☑	A97	H97	DEFAULT0
1-CVOR	☑	☑	☑	A97	H97	DEFAULT0
1E-PACU	☑	☑	☐	A97	H97	DEFAULT0
1E-PEDS ER	☑	☑	☑	A97	H97	DEFAULT0
1E-PREOP	☑	☑	☑	A97	H97	DEFAULT0
1-MPACU	☑	☑	☐	A97	H97	DEFAULT0
1-POCT	☑	☑	☑	A97	H97	DEFAULT0
1-STICU 1	☑	☑	☑	A97	H97	DEFAULT0
1-STICU 2	☑	☑	☐	A97	H97	DEFAULT0
2M-RESP.	☑	☑	☑	A97	H97	DEFAULT0
2W-ORTHO	☑	☑	☑	A97	H97	DEFAULT0
3N-NEONATAL	☑	☑	☐	A97	H97	DEFAULT0

6. ***Update the Software in the i-STAT 1 Analyzer***
   - Go to the location where the i-STAT 1 Analyzers you wish to update are located.
   - Press the On/Off button on the analyzer to turn the display on.
   - Press the Menu key to bring up the Administration Menu.
   - Press 7 for Utility. The Utility menu may be password protected. Enter the password or press the Enter key if no password has been specified.
   - From the Utility Menu, select **3-Receive Software**. The "Waiting to Send" message will appear on the analyzer display.
   - Place the analyzer in the downloader or downloader/recharger. A Communication in Progress message will appear on the screen. After this message disappears, the analyzer display will stay blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the procedure.
   - A scrolling bar will then appear on the analyzer display. This bar indicates that the software is uploading into the analyzer. Do not move the analyzer while the scrolling bar appears on the display screen. When the upload process is complete, the scrolling bar will disappear and the analyzer display will again go blank for approximately 5-10 seconds. Please note that this blank screen is normal analyzer behavior during this part of the process.

- A Waiting to Send message followed by a Communication in Progress message will then appear on the analyzer display. After these messages disappear, the analyzer display will go blank, and the update process is complete.

7. ***Verify the Update***

    - Run an external Electronic Simulator on updated Analyzers and check the Analyzer Status page for the new Application software and/or CLEW.

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Windows is a registered trademark of Microsoft Corporation.

i-STAT

Important!

i-STAT® 1 System Manual Update

As of April 2008, the current i-STAT® 1 System Manual has been updated. Please **ADD** and **DELETE** the sheets as listed below. Once the updates have been completed these instructions may be discarded. If you have any questions about these instructions, please contact your i-STAT support provider.

A ▶ ADD SHEET ◀ D DESTROY SHEET

	Item	Art#
A▶	Creatinine Information Sheet	714183-00K
◀D	Creatinine Information Sheet	714183-00J (or lower)
A▶	Total Carbon Dioxide/TCO_2 Information Sheet	716661-00D
◀D	Total Carbon Dioxide/TCO_2 Information Sheet	716661-00C (or lower)
A▶	i-STAT 1 System Manual Section 6: i-STAT 1 Downloader	714368-00F
◀D	i-STAT 1 System Manual Section 6: i-STAT 1 Downloader	714368-00E (or lower)
A▶	i-STAT 1 System Manual Section 21: Downloader Programming and Wiring	714383-00E
◀D	i-STAT 1 System Manual Section 21: Downloader Programming and Wiring	714383-00D (or lower)
A▶	Technical Bulletin: Analyzer Coded Messages	714260-00G
◀D	Technical Bulletin: Analyzer Coded Messages	714260-00F (or lower)
A▶	Technical Bulletin: Proficiency Testing on the i-STAT System	714262-00P
◀D	Technical Bulletin: Proficiency Testing on the i-STAT System	714262-00N (or lower)
A▶	Technical Bulletin: April 2008 Update to the Central Data Station Version 5*	721106-00A
A▶	Technical Bulletin: The i-STAT System and Waived Status	721018-00B
◀D	Technical Bulletin: The i-STAT CHEM8+ Cartridge: Waived Status	721018-00A

*Required for CDS Version 5 Users Only

END

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CREATININE/CREA

Creatinine is measured amperometrically. Creatinine is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide (H_2O_2). The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample creatinine concentration.

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^{-}$$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[1]

If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

INTENDED USE

The test for creatinine, as part of the i-STAT System, is intended for use in the *in vitro* quantification of creatinine in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of creatinine, a list of reactive ingredients is indicated below:

Reactive Ingredient	Biological Source
Creatinine	N/A
Creatine Amidinohydrolase	*Actinobacillus sp.*
Creatinine Amidohydrolase	Microbial
Sarcosine Oxidase	Microbial

Metrological Traceability

The i-STAT System test for creatinine measures creatinine amount-of-substance concentration in the plasma fraction of arterial, venous, or capillary whole blood (dimension $\mu mol\ L^{-1}$) for *in vitro* diagnostic use. Creatinine values assigned to i-STAT's controls and calibration verification materials are traceable to the U.S. National Institute of Standards and Technology (NIST) standard reference material SRM909.

i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range
Creatinine/Crea	mg/dL	0.2 – 20.0	0.6 – 1.3[2]
	µmol/L	18 – 1768	53 – 115

To convert a creatinine result from mg/dL to µmol/L, multiply the mg/dL value by 88.4.

The i-STAT reference ranges for whole blood listed above are similar to reference ranges derived from serum or plasma measurements with standard laboratory methods.

The reference range programmed into the analyzer and shown above is intended to be used as a guide for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

* The i-STAT System can be configured with the preferred units.

Clinical Significance

Elevated levels of creatinine are mainly associated with abnormal renal function and occur whenever there is a significant reduction in glomerular filtration rate or when urine elimination is obstructed. The concentration of creatinine is a better indicator of renal function than urea or uric acid because it is not affected by diet, exercise, or hormones.

The creatinine level has been used in combination with BUN to differentiate between prerenal and renal causes of an elevated urea/BUN.

Performance Characteristics

The typical performance data summarized below were collected in health care facilities by professionals trained in the use of the i-STAT System and comparative methods. Clinical settings vary and some may require different performance characteristics to assess renal function status than others (e.g., medication dosing, intravenous contrast use, and outpatient clinic). If deemed necessary by a health care facility, performance data should be obtained in specific clinical settings to assure patients' needs are met.

Precision data were collected in multiple sites following the protocol recommended by Abbott Point of Care. The means, SDs and CVs from 20 replicates at each site were averaged. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[3]. Venous blood samples, collected in lithium or sodium heparin Vacutainer® tubes, and arterial blood samples, collected in blood gas syringes, were analyzed in duplicate on the i-STAT System. A portion of each specimen was centrifuged, and the separated plasma was analyzed on the comparative method.

Deming regression analysis[4] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Interference studies were based on CLSI guideline EP7.[5]

---

*The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[5] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mg/dL)

Aqueous Control	Mean	SD	%CV
Level 1	4.33	0.131	3.0
Level 3	0.81	0.039	4.8

Method Comparison (mg/dL)

	Roche Integra 800	Beckman LX20	J & J Vitros 950	Dade Dimension RxL
n	30	58	31	36
Sxx	0.029	0.141	0.04	0.04
Syy	0.112	0.143	0.12	0.06
Slope	0.929	0.960	0.948	0.964
Int't	0.237	0.022	0.206	0.100
Syx	0.204	0.261	0.165	0.123
Xmin	0.4	0.7	0.5	0.5
Xmax	10.3	20.0	7.2	5.7
r	0.997	0.996	0.991	0.986

Cartridge Comparison

The performance characteristics of the sensors are equivalent in all cartridge configurations. System difference analysis was performed on 39 patient samples using the i-STAT CHEM8+ and i-STAT Crea cartridges. In the 0.42-2.50 mg/dL range, the average difference was -0.01. In the 2.50-9.08 mg/dL range, the average difference was -0.04.

Factors Affecting Results*

Interferent	Effect
Acetaminophen	Creatinine results will increase by approximately 0.25 mg/dL (22 µmol/L) per every 1 mmol/L of acetaminophen.
Ascorbate	0.227 mmol/L ascorbate will cause a 0.7 mg/dL (62 µmol/L) increase in creatinine.
Bromide	100 mg/dL (12.5 mmol/L) bromide will increase creatinine by 0.8 mg/dL (71 µmol/L) from an initial creatinine concentration of 1.0 mg/dL (88 µmol/L).
CO_2	For Crea values below 2 mg/dL: For PCO_2 values above 40 mmHg, the values are increased by 6.9% for every 10 mmHg For PCO_2 values below 40 mmHg, the values are decreased by 6.9% for every 10 mmHg [Cr]corrected = [Cr]istat X { 1 - (0.069 X [(PCO_2 -40)/10]) } For Crea values above 2 mg/dL: For PCO_2 values above 40, the values are decreased by 3.7% for every 10 mmHg For PCO_2 values below 40, the values are increased by 3.7% for every 10 mmHg Cr]corrected = [Cr]istat X { 1 - (0.037 X [(40 - PCO_2)/10]) }
Creatine	5 mg/dL (382 µmol/L) creatine will cause a 0.20 mg/dL (18 µmol/L) increase in Creatinine. For clinical situations in which creatine may be elevated, see note (1) below.

Interferent	Effect
N-acetylcysteine	16.6 mmol/L N-acetylcysteine will cause a 0.4 mg/dL (36 µmol/L) increase in creatinine.
Hydroxyurea (Droxia®, Hydrea®)	Hydroxyurea may cause significant errors in the measurement of creatinine with the i-STAT System. Use an alternative method to measure creatinine when patients have been administered hydroxyurea. See note (2) below for typical uses of this drug and note (3) below for details of the interference.

Notes:

(1) The normal range of creatine concentration in plasma is 0.17 – 0.70 mg/dL (13 – 53 µmol/L) in males and 0.35 – 0.93 mg/dL (27 – 71 µmol/L) in females[6]. Creatine may be elevated in patients using creatine supplements, experiencing muscle trauma or other primary or secondary myopathies, taking statins for hyperlipidemia control, or in patients with hyperthyroidism or a rare genetic defect of the creatine transporter protein.

(2) Hydroxyurea is a DNA synthesis inhibitor used in the treatment of various forms of cancer, sickle cell anemia, and HIV infection. This drug is used to treat malignancies including melanoma, metastatic ovarian cancer, and chronic myelogenous leukemia. It is also used in the treatment of polycythemia vera, thrombocytopenia, and psoriasis. At typical doses ranging from 500 mg to 2 g/day, concentrations of hydroxyurea in patients' blood may be sustained at approximately 100 to 500 µmol/L. Higher concentrations may be observed soon after dosing or at higher therapeutic doses.

(3) For every 100 µmol/L hydroxyurea in the whole blood sample, creatinine will be increased by approximately 1.85 mg/dL (164 µmol/L), up to a whole blood hydroxyurea concentration of at least 921 µmol/L (maximum concentration tested). The magnitude of the bias is independent of the creatinine level over a range of at least 1.0 mg/dL (88 µmol/L) to 12.4 mg/dL (1096 µmol/L).

Bicarbonate up to 40 mmol/L, bilirubin up to 20 mg/dL (342 µmol/L), calcium up to 5.0 mg/dL (1.25 mmol/L), dopamine up to 13 mg/dL (0.85 mmol/L), methyldopa up to 2.5 mg/dL (118.4 µmol/L), salicylate up to 77.5 mg/dL (4.34 mmol/L), sarcosine up to 1.0 mmol/L, and uric acid up to 20 mg/dL (1190 µmol/L) were tested and found not to interfere with creatinine results.

*It is possible that other interfering substance may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. D. S. Young, *Effects of Drugs on Clinical Laboratory Tests*, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

2. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics 4th Edition*, CA Burtis, ER Ashwood, DE Bruns, ed., Elsevier Saunders Inc., 2006, page 2264.

3. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

4. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

5. CLSI. *Interference Testing in Clinical Chemistry; Proposed Guideline.* CLSI document EP7-P (ISBN 1-56238-020-6). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087, 1986.

6. *Tietz Textbook of Clinical Chemistry 3rd Edition*, CA Burtis and ER Ashwood, ed., WB Saunders Company, 1999, page 1808.

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TOTAL CARBON DIOXIDE/ (TCO_2)

Intended Use

The test for TCO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of total carbon dioxide in arterial, venous, or capillary whole blood.

Method Explanation

The measured TCO_2 test method is calibrated to the International Federation of Clinical Chemistry (IFCC) TCO_2 reference method[1] with an algorithm, based on the Henderson-Hasselbalch equation, which uses pH, PCO_2, and ionic strength (Na) measurements.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibration solution that contains known concentrations of analytes and preservatives. For cartridges that contains sensors for the measurement of TCO_2, a list of reactive ingredients is indicated below:

Reactive Ingredient
Carbon Dioxide (CO_2)

Metrological Traceability

The i-STAT System test for total carbon dioxide (TCO_2) measures the amount-of-substance total concentration of all forms of carbon dioxide in the plasma fraction of arterial, venous, or capillary whole blood (dimension mmol L^{-1}) for *in vitro* diagnostic use. TCO_2 values assigned to i-STAT System controls and calibration verification materials are traceable to the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Reference Measurement Procedure for Substance Concentration Determination for Total Carbon Dioxide in Blood, Plasma or Serum.[1] i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from Abbott Point of Care Inc..

Expected Values

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE *(arterial)*	REFERENCE RANGE *(venous)*
Total Carbon Dioxide/TCO_2	mmol/L	5 – 50	23 – 27*	24 – 29*

*Calculated from Siggard-Andersen nomogram.[2]

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The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender, and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

TCO_2 is a measure of carbon dioxide which exists in several states: CO_2 in physical solution or loosely bound to proteins, bicarbonate (HCO_3) or carbonate (CO_3) anions, and carbonic acid (H_2CO_3). Measurement of TCO_2 as part of an electrolyte profile is useful chiefly to evaluate HCO_3 concentration. TCO_2 and HCO_3 are useful in the assessment of acid-base imbalance (along with pH and PCO_2) and electrolyte imbalance.

Calculated and Measured (Traceable) TCO_2

The calculated TCO_2 provided by the i-STAT System is determined from the measured and reported values of pH and PCO_2 according to a simplified and standardized form of the Henderson-Hasselbalch equation.[3]

$$TCO_2 = HCO_3 + 0.03\ \boldsymbol{P}CO_2$$

This calculated TCO_2 measurement is metrologically traceable to the i-STAT pH and PCO_2 measurements, which are in turn traceable to primary standard reference materials for pH and PCO_2. Like all calculated parameters reported by the i-STAT System, the user can independently determine TCO_2 values from the reported pH and PCO_2 measurements using a combination of the equation for HCO_3 given in the PCO_2 Cartridge and Test Information (CTI) sheet, and the equation for TCO_2 above.

On the CHEM8+ cartridge, TCO_2 is metrologically traceable to the IFCC TCO_2 reference method. The implication of direct traceability to this TCO_2 reference method – and not to pH and PCO_2 standard reference materials – is subtle but significant: the CHEM8+ is independent of the pH and PCO_2 traceability. Given the metrological traceability of the CHEM8+ TCO_2 measurement, the traceable TCO_2 is considered to be a measured analyte

Performance Characteristics

Precision data were collected in multiple sites following the protocol recommended by Abbott Point of Care. The means, SDs and CVs from 20 replicates at each site were averaged. The average statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[4]. Venous blood samples were collected in lithium heparin evacuated tubes from hospital patients. The whole blood samples were run in duplicate on the i-STAT System. The samples were then centrifuged to obtain plasma and analyzed in duplicate on the comparative instrument. All samples were analyzed on both methods within 15 minutes of each other.

Deming regression analysis[5] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the first data set. Sxx and Syy refer to the estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively. Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons may vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables. For TCO_2, values measured on serum or plasma by chemistry analyzers may be slightly lower than TCO_2 calculated from pH and PCO_2 due to loss of CO_2 during non-anaerobic handling.[6] Up to 6 mmol/L CO_2 can be lost per hour by exposure of the sample to air.[7]

*The usual warning relating to the use of regression analysis is summarized here as a reminder. For any analyte, "if the data is a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from estimates may be invalid",[4] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method ranges in overcoming the problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmol/L)

Aqueous Control	Mean	SD	%CV
Level 1	17.4	0.62	3.6
Level 3	34.6	0.62	1.8

Method Comparison (mmol/L)

	TCO_2 (Calculated) IL BGE	TCO_2 (Calculated) Beckman Coulter CX®3	TCO_2 (Measured) Beckman Coulter LX®20
n	62	51	35
Sxx	0.40	0.55	0.48
Syy	0.84	0.55	0.60
Slope	1.136	1.155	1.152
Int't	-4.1	-2.6	-1.5
Sy.x	1.38	1.56	0.96
Xmin	19.3	18.3	21
Xmax	43.9	36.1	35
r	0.965	0.935	0.943

Cartridge Comparison

Performance characteristics for TCO_2 are equivalent in all cartridge configurations. System difference analysis was performed on 40 patient samples using the i-STAT CHEM8+ and i-STAT EC8+ cartridges. In the 14-30 mmol/L range, the average difference was -0.7 mmol/L.

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes TCO_2 to be under-estimated. The use of partial draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for use with the i-STAT System because of the potential for decreased TCO_2 values. Under-filling blood collection tubes may also cause decreased TCO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood samples to stand (without exposure to air) before testing allows TCO_2 to be over-estimated, due to metabolic processes.

*It is possible that other interfering substances may be encountered.

References

1. IFCC Reference Measurement Procedure for Substance Concentration Determination for Total Carbon Dioxide in Blood, Plasma or Serum (IFCC 2001/3). Clin. Chem. Lab Med., 39(3), 2001.
2. E.L. Pruden, O. Siggard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994).
3. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*. CLSI document C46-A [ISBN 1-56238-444-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.
4. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline*. CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.
5. P.J. Cornbleet and N. Gochman, "Incorrect Least Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).
6. J.P.J. Ungerer, M.J. Ungerer, and W.J.H. Vermaak, Discordance Between Measured and Calculated Total Carbon Dioxide, Clinical Chemistry 36.12, 1990. 2093-2096.
7. M.G. Scott, J. Heusel, V.A. LeGrys, and O. Siggard-Andersen, Electrolytes and Blood Gases, in Tietz Textbook of Clinical Chemistry, Third Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1999).

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i-STAT 1 DOWNLOADER 6

Function

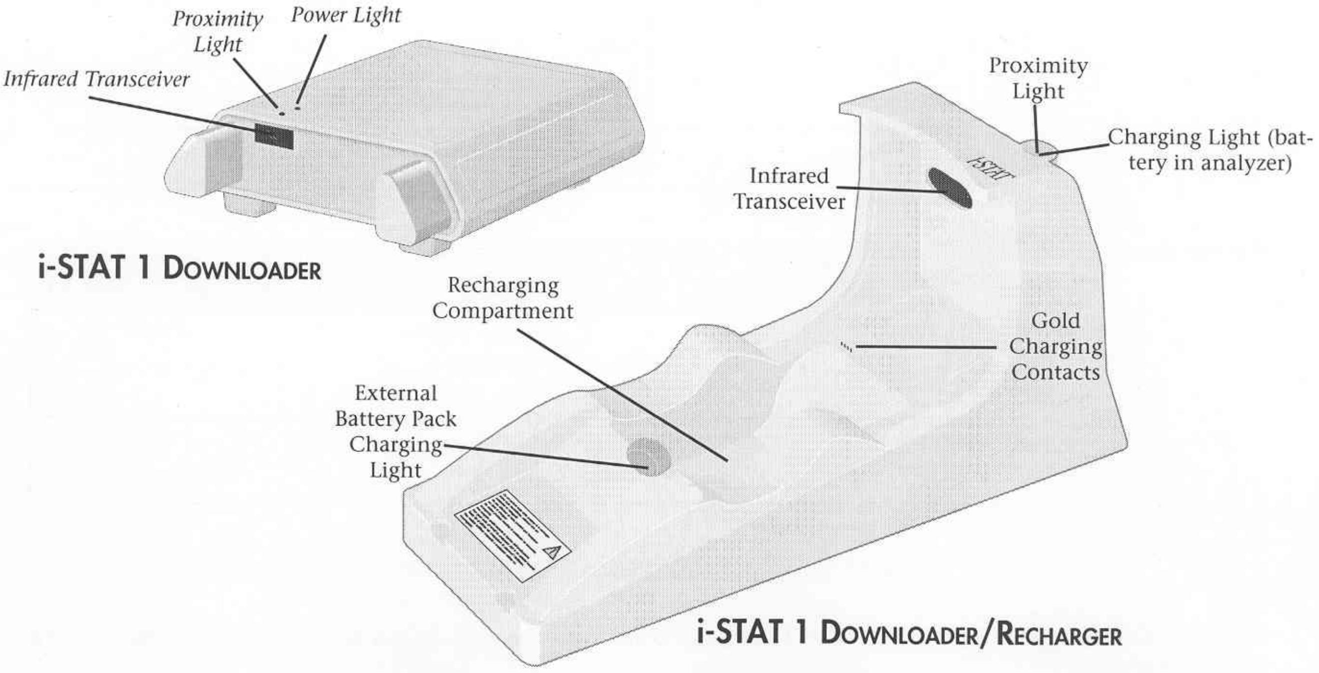
The Downloader converts infrared transmissions of test records from the analyzer to electrical form and transmits (uploads) them to the Data Manager. The Downloader also converts electrical signals from the Central Data Station to infrared transmissions, which are transmitted (downloaded) to the analyzer. Transmission is automatic when an analyzer is placed in a Downloader.

The Downloader comes in two formats:

- ✧ Downloader: A low-profile table-top unit with "arms" between which the analyzer is placed, and
- ✧ Downloader/Recharger (DR): a cradle that the analyzer is placed within.

Both Downloader formats are available for use with direct wiring (serial format) or ethernet cabling (network format). Unless indicated otherwise, references to the Downloader apply to the Downloader/Recharger as well.

The Downloader/Recharger can recharge a rechargeable battery in the analyzer. If the analyzer contains a rechargeable battery, the battery begins recharging automatically as soon as the analyzer is placed in the Downloader/Recharger. The Downloader/Recharger also has a compartment for recharging a rechargeable battery outside the analyzer.


Proximity Light
Power Light
Infrared Transceiver
Proximity Light
Charging Light (battery in analyzer)
Infrared Transceiver
Recharging Compartment
Gold Charging Contacts
External Battery Pack Charging Light

i-STAT 1 DOWNLOADER

i-STAT 1 DOWNLOADER/RECHARGER

Specifications

Specification	Downloader	Downloader/Recharger
Size	5.25in (13.3cm) Wide 6.75in (17.2cm) Long 2.13in (5.4cm) High	4.12in (10.4cm) Wide 10.25in (26.cm) Long 5.00in (12.7cm) High
Weight	0.6 lbs (0.27kg)	1.2 lbs (0.55kg)
Power	AC-DC power adapter or PC/Downloader adapter. Input 12V ⎓	AC-DC power adapter or PC/Downloader adapter.* Input 12V ⎓
Operating Temperature	0 to 40°C 32 to 104°F	0 to 40°C 32 to 104°F
Storage Temperature	-20 to 50°C -4 to 122°F	-20 to 50°C -4 to 122°F
Pollution Degree (Allowable ambient pollution level)	2	2
Installation Category (Allowable overvoltage specification)	2	2
Communication To Central Data Station and other equipment	Serial (RS232), or Ethernet	Serial (RS232), or Ethernet
Communication Link To and From Analyzer	Infrared Transceiver	Infrared Transceiver
Indicator LEDs		
Power	Green	NA
Proximity	Red	Blue
Charge	NA	Red/Green
Configuration	By host computer	By host computer

Power Supply

Specification	Downloader and Downloader/Recharger
Input	100 - 240V~ 47 - 63 Hz .9 - .5A
Output	12V⎓ 3A max

* Recharge feature cannot be used in this configuration.

Running Cartridges in an Analyzer Docked in a Downloader/Recharger

All current i-STAT Cartridges may be run in an analyzer that is docked in a Downloader/Recharger.

Downloader/ Recharger Indicator LEDs

Analyzer Battery LED (near top of Downloader/Recharger)	
Off	No Rechargeable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging
Spare Battery (near middle of Downloader/Recharger)	
Off	No Rechargeable Battery
Green	Trickle Charging

Power Requirements

The Downloaders require one power outlet. The Downloader and Downloader/Recharger must be used with the AC power supply adapter supplied with them. The Downloader and Downloader/Recharger have different power supply adapters that are not interchangeable. The Downloaders are capable of supplying power to the portable printer which reduces the number of power outlets required in the downloading and printing area.

DR Affect on Ambient Operating Temperature Range

The operating temperature for an i-STAT 1 Analyzer is 18°C to 30°C. The DR and Rechargeable Battery may raise the temperature of the i-STAT 1 Analyzer 2°C-3°C relative to the ambient temperature if:

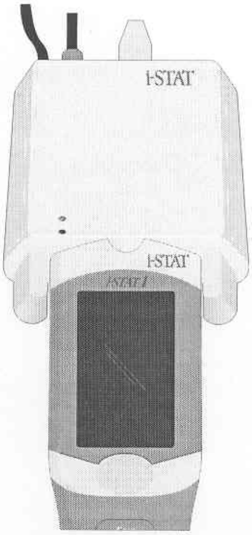
- The Analyzer is frequently lifted and replaced into the DR
- Multiple thermally controlled cartridges are run in the Analyzer while it is in the DR.

Programming and Connections

Details for programming the Network Downloaders can be found in the Downloader Programming and Wiring section of this manual. Diagrams and instructions for connecting peripheral components to the Downloader can also be found in the Downloader Programming and Wiring section.

Cautions

The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).



Users should not connect the Downloader or the Downloader/Recharger to a medical electrical system.

Do not place metal objects on or near the exposed gold charging contacts.

Be sure to install all cables and power supplies so they do not pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways. The AC power supply adapter plug acts as the disconnect device for the Downloader and Downloader/Recharger and, therefore, the socket outlet must be installed (or located) near the Downloader or Downloader/Recharger and must be easily accessible.

Only i-STAT provided printers may be connected to the Downloader printer port.

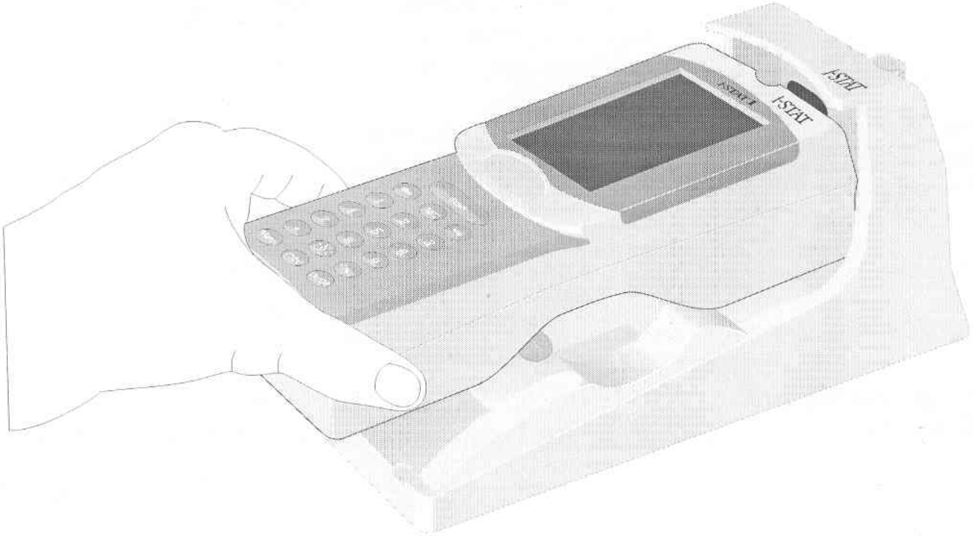
An ethernet cable and serial (DB9) cable may NOT be connected to the Downloader at the same time.

Transmitting Data from Downloader to the Data Manager

To transmit through a Downloader to the Data Manager, place the analyzer between the arms on the front of the Downloader with the test strip port end touching the Downloader. When properly aligned the red proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.

Transmitting Data from Downloader / Recharger to the Data Manager

To transmit data through a Downloader/Recharger, place the analyzer in the Downloader/Recharger's cradle. When properly aligned, the blue proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.



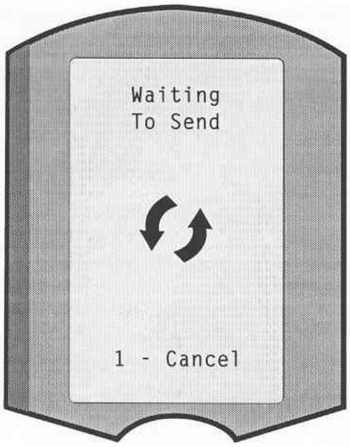
Transmitted Information

The following information is transmitted from the analyzer with each test record:

- The date and time the test was performed
- Operator ID and Patient ID or Quality Test fluid lot number
- All information entered by the operator, such as lot numbers, sample type and comment codes
- Result(s)
- Serial number of the analyzer
- Uses count of the analyzer
- Application software version in the analyzer
- Standardization software in the analyzer

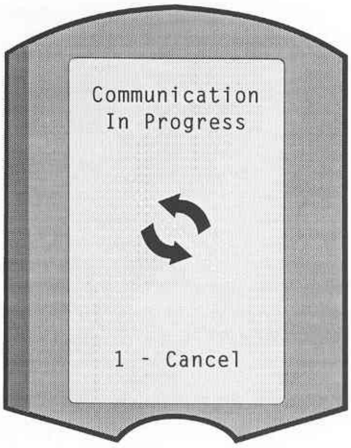
Troubleshooting

The analyzer displays "Waiting to Send" until communication is established with the Central Data Station. When communication is established the message changes to "Communication in Progress" and the arrows circle until upload is complete. If the message does not change from "Waiting to Send" or if the Analyzer Status screen reports unsent results after the upload, refer to Support Services in the Troubleshooting section.



Waiting
To Send

1 - Cancel



Communication
In Progress

1 - Cancel

Charge Battery Before Use

Put new rechargeable battery in external charging bay on the i-STAT®1 Downloader/Recharger for 40 hours. Battery will be 100% charged and ready for use. Analyzer with disposable batteries may be placed on Downloader/Recharger to download data until rechargeable battery is ready.

Keep Battery Charged

Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by either (1) keeping the rechargeable battery in an Analyzer that is periodically on the Downloader/Recharger, or (2) store the rechargeable battery separately in the external charging bay on the Downloader/Recharger.

Rechargeable Battery Life

Rechargeable batteries normally exhibit reduced charge capacity after a reasonable lifetime or number of discharge-recharge cycles. i-STAT rechargeable batteries come with a service life expectancy of 15 months from the date of manufacture which appears on the battery. While the battery may last longer in your application, you may need to purchase a new rechargeable battery to replace a failing battery after the 15 month lifetime.

Charging the Rechargeable Battery

Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger.

No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.

Charging Rechargeable Battery in External Recharge Compartment

Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.

STEP	ACTION
1	The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger. With the label with the Downloader facing up and the electrical contact end of the pack facing the contacts in the battery compartment, insert the pack into the compartment as shown on the label.
2	To remove the battery after it is charged, back the pack out of the compartment.

Full recharge from a discharged state takes approximately 40 hours

Caution

If you are using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients. A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

DOWNLOADER PROGRAMMING AND WIRING 21

Programming the Network Downloaders

This section includes procedures to configure the network Downloaders to transmit data between the i-STAT 1 Analyzers and the Central Data Station (CDS) program as well as from other peripheral devices to the CDS or other PC.

Preparation

1. Determine for each Downloader: IP Address, Gateway Address, and Subnet Mask.
2. Determine for the Workstation: The IP Address of the Point-of-Care Central Workstation and the Central Data Station service port for i-STAT 1 Analyzer transmissions (typically 6004).

Configure a Terminal Session

1. Run a terminal emulation program, such as HyperTerminal, and choose the following port settings:

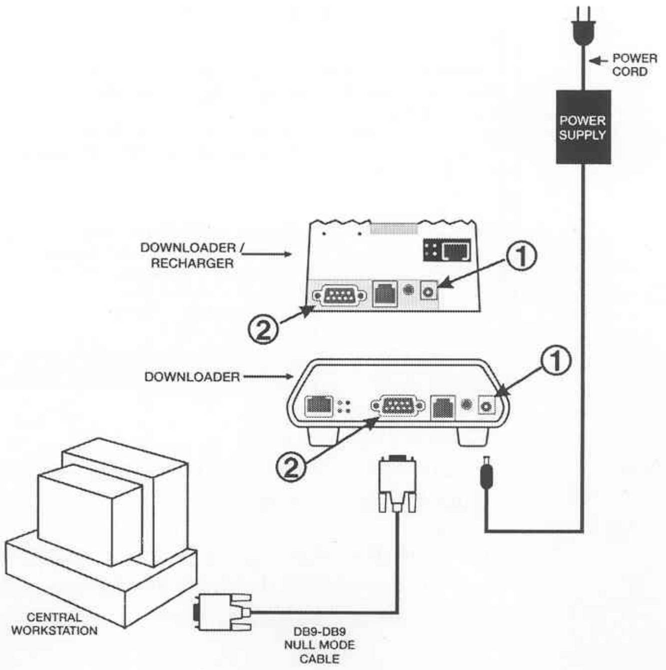
Bits per second: **9600**
Data bits: **8**
Parity: **None**
Stop Bits: **1**
Flow Control: **None**

Connect to and Program the Downloader

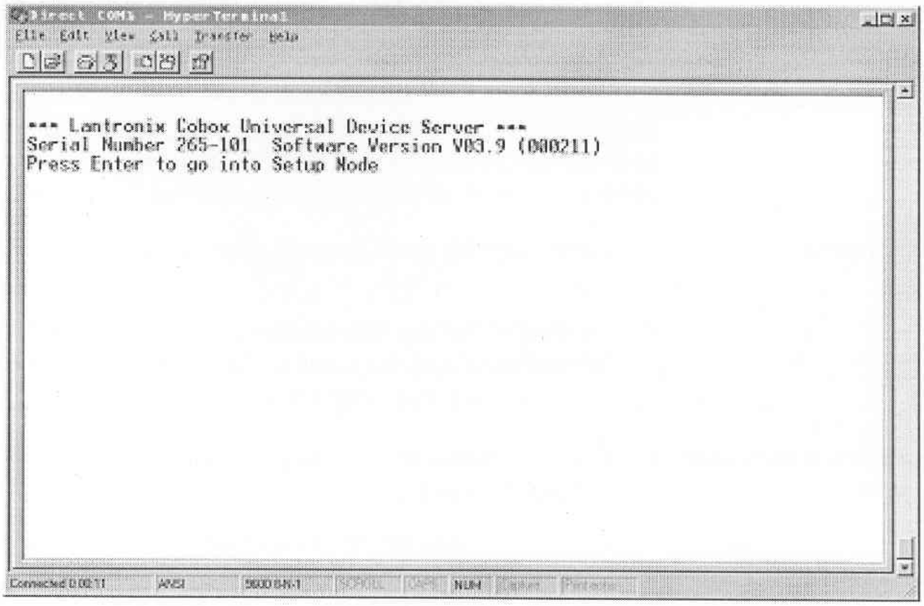
1. Connect one end of a Null-Modem Cable to the DB9 Port on the Downloader and connect the other end to the COM port selected in the session above to the Point-of-Care Central Workstation as shown below. **Do not apply power to the Downloader at this time.**

① Power In

② DB9

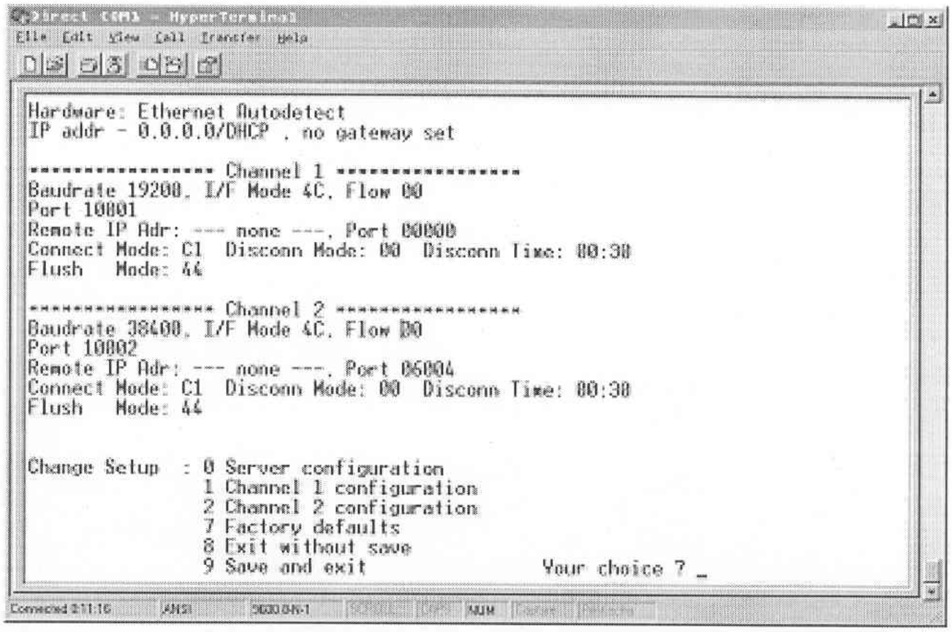


2. While holding down the x key on the PC keyboard, apply power to the Downloader. When the following screen is displayed release the x key:


Direct COM1 - HyperTerminal
File Edit View Call Transfer Help
Connected 0:02:11
ANSI
9600 8-N-1
SCROLL
CAPS
NUM

```
*** Lantronix Cobox Universal Device Server ***
Serial Number 265-101  Software Version V03.9 (000211)
Press Enter to go into Setup Mode
```

3. Press the Enter key immediately to enter the Setup Mode:


Direct COM1 - HyperTerminal
File Edit View Call Transfer Help
Connected 0:11:16
ANSI
9600 8-N-1
SCROLL
CAPS
NUM

```
Hardware: Ethernet Autodetect
IP addr - 0.0.0.0/DHCP , no gateway set

***************** Channel 1 *****************
Baudrate 19200, I/F Mode 4C, Flow 00
Port 10001
Remote IP Adr: --- none ---, Port 00000
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

***************** Channel 2 *****************
Baudrate 38400, I/F Mode 4C, Flow 00
Port 10002
Remote IP Adr: --- none ---, Port 06004
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44


Change Setup  : 0 Server configuration
                1 Channel 1 configuration
                2 Channel 2 configuration
                7 Factory defaults
                8 Exit without save
                9 Save and exit                 Your choice ? _
```

Configure Server Parameters

Each network Downloader requires a static IP Address, a Gateway Address, and, if required, a Subnet Mask.

Note: **Failure to assign a <u>static</u> IP address to the downloader could result in an i-STAT 1 Analyzer being programmed with an inappropriate customization profile.**

The following describes how to configure the network Downloader's server parameters.

1. Determine the following site specific information for this Downloader:
    - IP Address (Example: 10.10.12.142 used below)
    - Gateway Address (Example: 10.10.12.1 used below)
    - Netmask (Example: 8 for 255.255.255.0 used below)
2. At the **Your choice?** prompt, Select **0** for Server Configuration and enter the information chosen for this Downloader.
3. At each of the prompts enter the bold-faced value.

    Note: If the information to be entered is the same as the default value, press the Enter key.

    - IP Address: (000)**10.**(000) **10.**(000)**12.**(000)**142**
    - Set Gateway IP Address: (N) **Y**
    - Gateway IP addr: (000)**10.**(000)**10.**(000)**12.**(000) **1**
    - Netmask: Number of Bits for Host Part (00) **8**

      Note: The Netmask is configured as the number of host bits required based on the subnet being used.
    - Change telnet config password: (N) **N**

Default Netmasks for Standard IP Networks

SUBNET MASK	HOST BITS	NETWORK TYPE
255.0.0.0	24	Class A
255.255.0.0	16	Class B
255.255.255.0	8	Class C

Netmasks for Other Networks

SUBNET MASK	HOST BITS	SUBNET MASK	HOST BITS
255.255.255.252	2	255.255.192.0	14
255.255.255.248	3	255.255.128.0	15
255.255.255.240	4	255.255.0.0	16
255.255.255.224	5	255.254.0.0	17
255.255.255.192	6	255.252.0.0	18
255.255.255.128	7	255.248.0.0	19
255.255.255.0	8	255.240.0.0	20
255.255.254.0	9	255.224.0.0	21
255.255.252.0	10	255.192.0.0	22
255.255.248.0	11	255.128.0.0	23
255.255.240.0	12	255.0.0.0	24
255.255.224.0	13		

Configure Channel 2

Channel 2 provides network access for the i-STAT 1 Analyzer data transmissions to the i-STAT Central Data Station running on the Data Manager. This section describes how to set up parameters for Channel 2.

1. Determine the following information:
    - The IP address of the Data Manager. (Example: 10.10.12.184)
    - The service port number set to receive transmissions from the i-STAT 1 Analyzer (typically 6004).
2. At the **Your choice ?** prompt, Select **2** (Channel 2 Configuration).
3. At each of the prompts enter the following bold-faced value:

    Note: If the information to be entered is the same as the default value, press the Enter key.

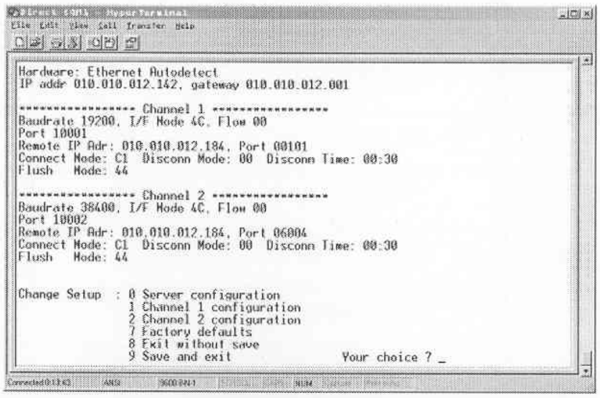
    - Baudrate (38400) ? **38400** (***must be set to 38400***)
    - I/F Mode (4C) ? (***press <Enter> key***)
    - Flow (00) ? (***press <Enter> key***)
    - Port No (10002) ? (***press <Enter> key***)
    - ConnectMode (C1) ? **C1** (***must be set to C1***)
    - Auto increment source port (N) ? **N** (***press <Enter> key***)
    - Remote IP Address : (000)**10**.(000)**10**.(000)**12**.(000) **184**

      Note: Set Remote IP Address to the IP Address of the Point-of-Care Central Workstation.
    - Remote Port (06004) ? **6004**

      Note: Remote Port refers to i-STAT 1 service port defined in the Central Data Station program.
    - DisConnMode (00) ? (***press <Enter> key***)
    - FlushMode (44) ? **44** (***must be set to "44"***)
    - DisConnTime (00:30) ? **00:30** (***Disconnect time must be 30 seconds)***
    - SendChar 1 (00) ? (***press <Enter> key***)
    - SendChar 2 (00) ? (***press <Enter> key***)

Verify and Save Settings

1. When the Summary screen appears, verify that the information you entered is correct. If it is not, fix the appropriate settings and continue.



```
Hardware: Ethernet Autodetect
IP addr 010.010.012.142, gateway 010.010.012.001

***************** Channel 1 *****************
Baudrate 19200, I/F Mode 4C, Flow 00
Port 10001
Remote IP Adr: 010.010.012.184, Port 00101
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44

***************** Channel 2 *****************
Baudrate 38400, I/F Mode 4C, Flow 00
Port 10002
Remote IP Adr: 010.010.012.184, Port 06004
Connect Mode: C1  Disconn Mode: 00  Disconn Time: 00:30
Flush   Mode: 44


Change Setup  : 0 Server configuration
                1 Channel 1 configuration
                2 Channel 2 configuration
                7 Factory defaults
                8 Exit without save
                9 Save and exit                  Your choice ? _
```

2. Save the settings by selecting **9** (Save and Exit) at the **Your choice ?** prompt.
3. Remove power and connect the Downloader in its intended location.

Troubleshooting

If a wrong number is entered, which cannot be corrected, press the **Enter** key until the session is completed and start from the beginning again.

WIRING THE DOWNLOADERS

Overview

This section includes diagrams to make a connection between the Downloaders and the Data Manager and to connect a printer to the Downloaders.

Caution

Only i-STAT provided printers may be connected to the Downloader printer port.

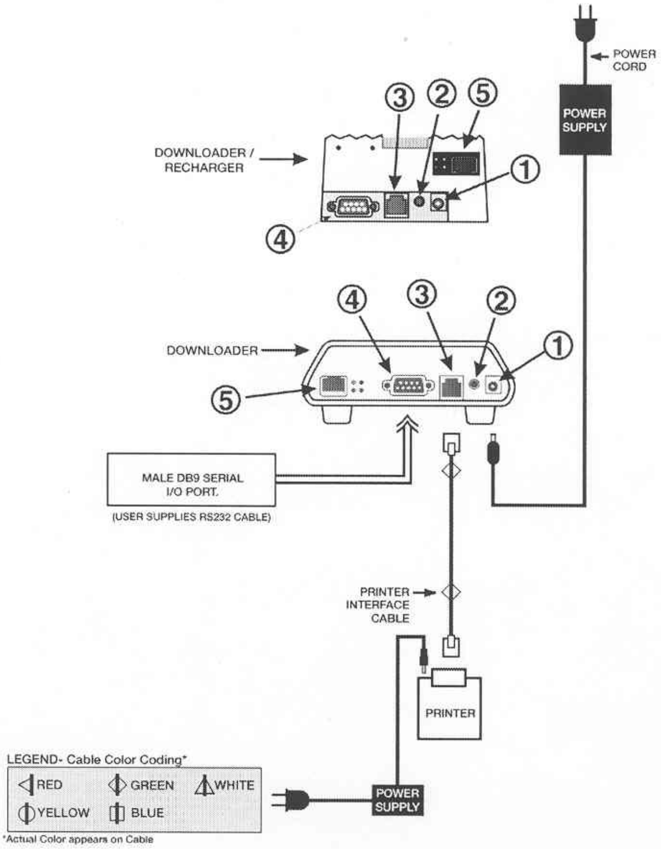
An ethernet cable and serial (DB9) cable may NOT be connected to the Downloader at the same time.

Connecting the Network Downloader

Option 1: The following diagram shows how to connect the portable printer to the network Downloader for communication. Parts required are:

- Printer Interface Cable
- Printer Power Adapter

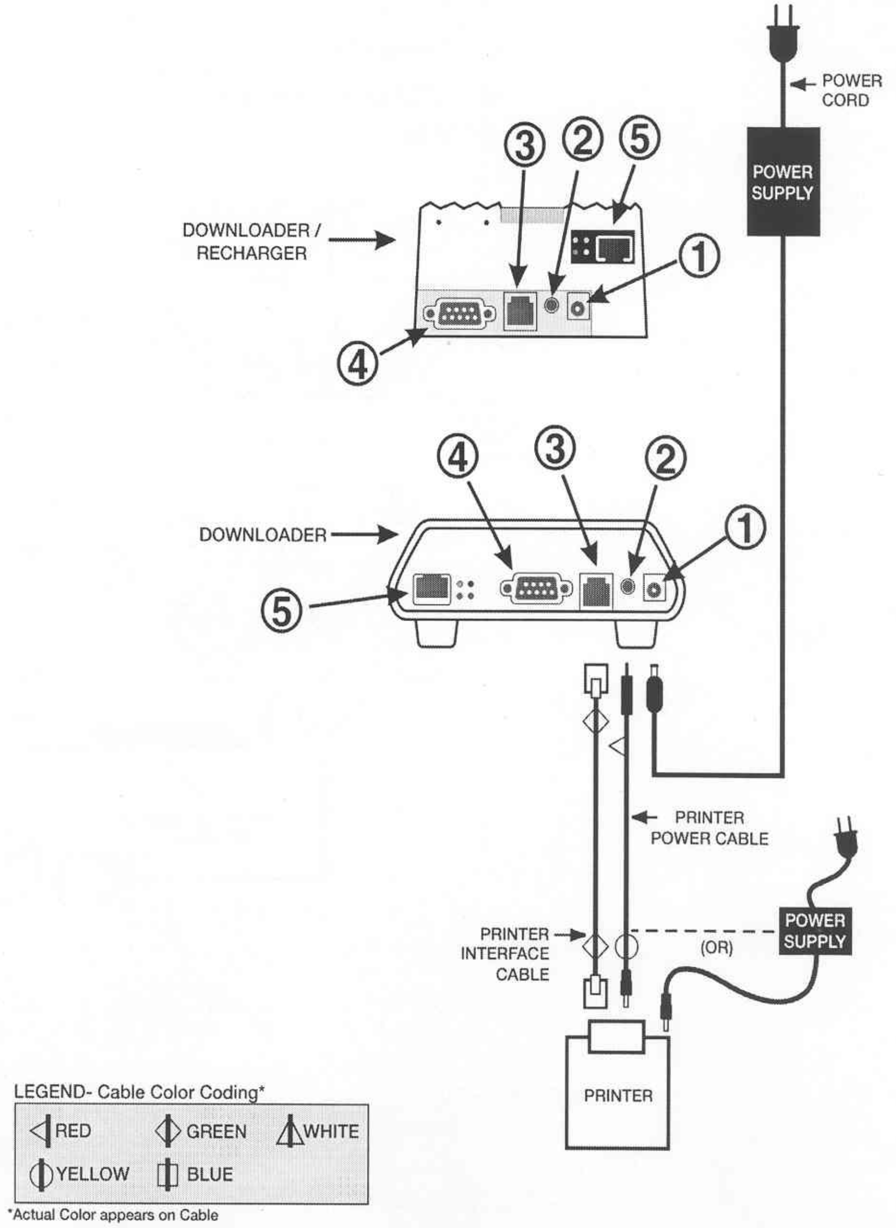
① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9
⑤ RJ45 (network)


POWER CORD
POWER SUPPLY
③ ② ⑤
DOWNLOADER / RECHARGER
①
④
④ ③ ②
DOWNLOADER
①
⑤
MALE DB9 SERIAL I/O PORT.
(USER SUPPLIES RS232 CABLE)
PRINTER INTERFACE CABLE
PRINTER
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable
POWER SUPPLY

Option 2: The following diagram shows how to connect the portable printer to the network Downloader for power and communication. Parts required are:

- Printer Interface Cable
- Printer AC Adapter or Printer Power Cable

① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9
⑤ RJ45 (network)


POWER CORD
POWER SUPPLY
③ ② ⑤
DOWNLOADER / RECHARGER
①
④
④ ③ ②
DOWNLOADER
①
⑤
PRINTER POWER CABLE
POWER SUPPLY
(OR)
PRINTER INTERFACE CABLE
PRINTER
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

Connecting the Serial Port Downloader

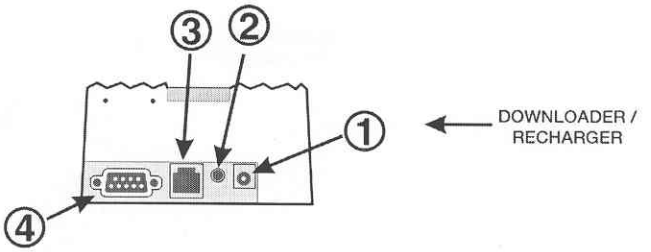
Option 1: The following option is for downloading/uploading only and can be used when there is no power outlet available for the Downloader or Downloader/Recharger.

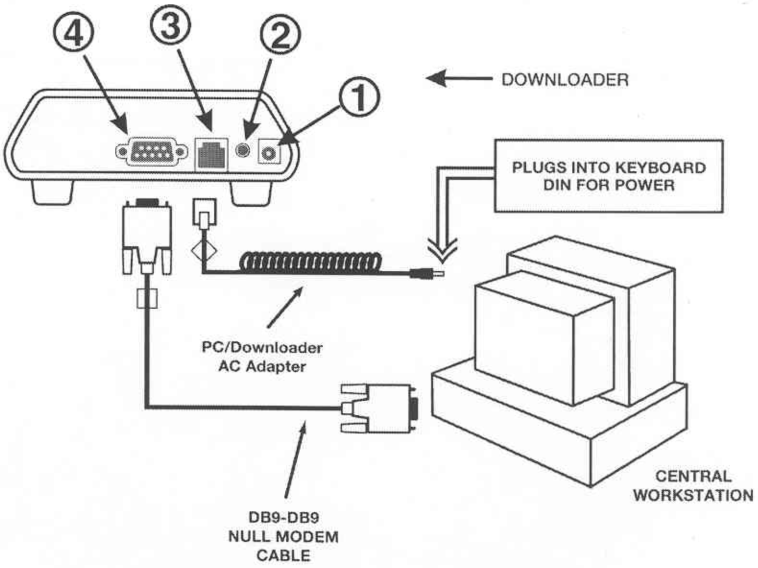
In this particular configuration, both recharging LED lights will be lit. The primary recharging LED will blink red and the alternate will be steady green. This is typical behavior, and does not indicate that any charging is taking place. In fact, batteries cannot be charged in the Downloader/Recharger in this configuration.

The following diagram shows how to connect a serial downloader locally to the Data Manager. Parts required are:

- PC/Downloader Adapter
- DB9-DB9 Null Modem Cable

① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9


③
②
①
④
DOWNLOADER / RECHARGER


④
③
②
①
DOWNLOADER
PLUGS INTO KEYBOARD DIN FOR POWER
PC/Downloader AC Adapter
CENTRAL WORKSTATION
DB9-DB9 NULL MODEM CABLE

LEGEND- Cable Color Coding*

◁ RED	◇ GREEN	△ WHITE
◇ YELLOW	▯ BLUE	

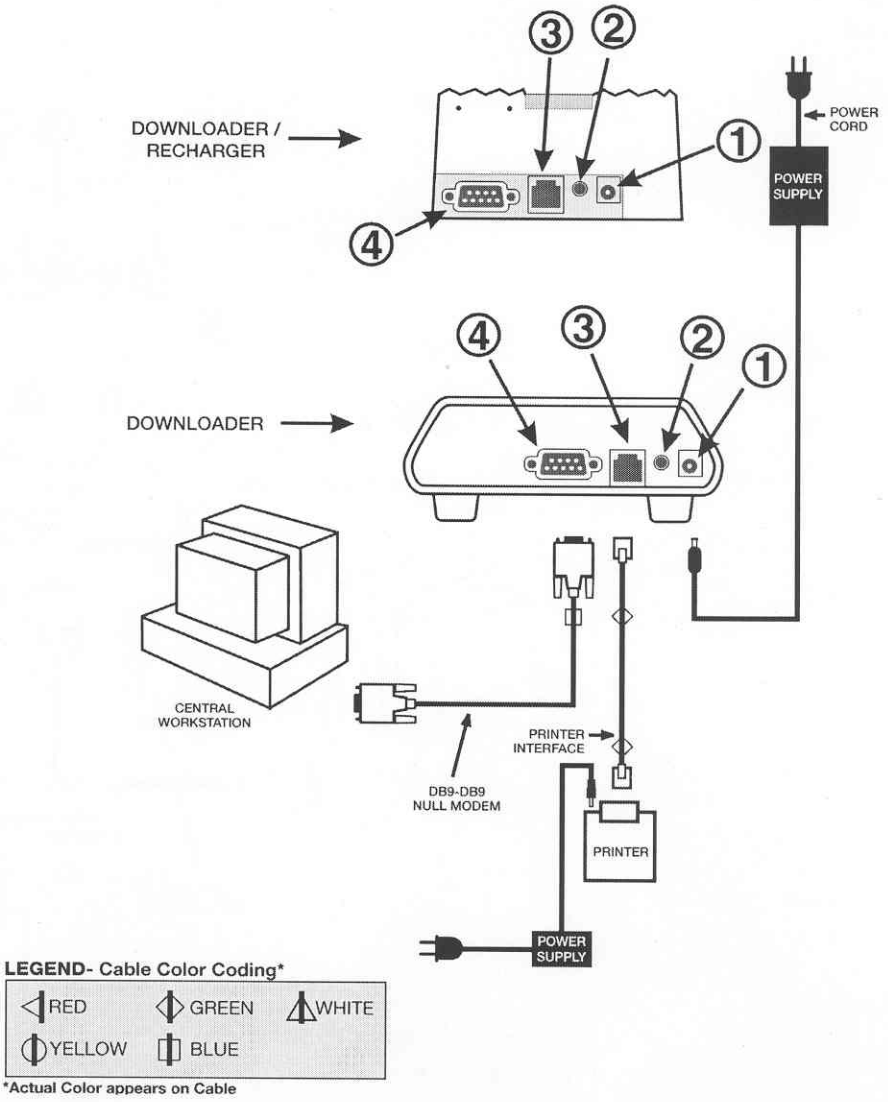
*Actual Color appears on Cable

*CANNOT POWER PCx DOCKING STATION OR PRINTER IN THIS MODE

Option 2: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for communication. Parts required are:

- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer AC Adapter

① Power In
② Power Out
③ RJ12 (printer interface)
④ DB9


③ ②
DOWNLOADER / RECHARGER
①
POWER CORD
POWER SUPPLY
④
④ ③ ② ①
DOWNLOADER
CENTRAL WORKSTATION
PRINTER INTERFACE
DB9-DB9 NULL MODEM
PRINTER
POWER SUPPLY
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

Option 3: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for power and communication. The printer can also be powered by its own AC adpater. Parts required are:

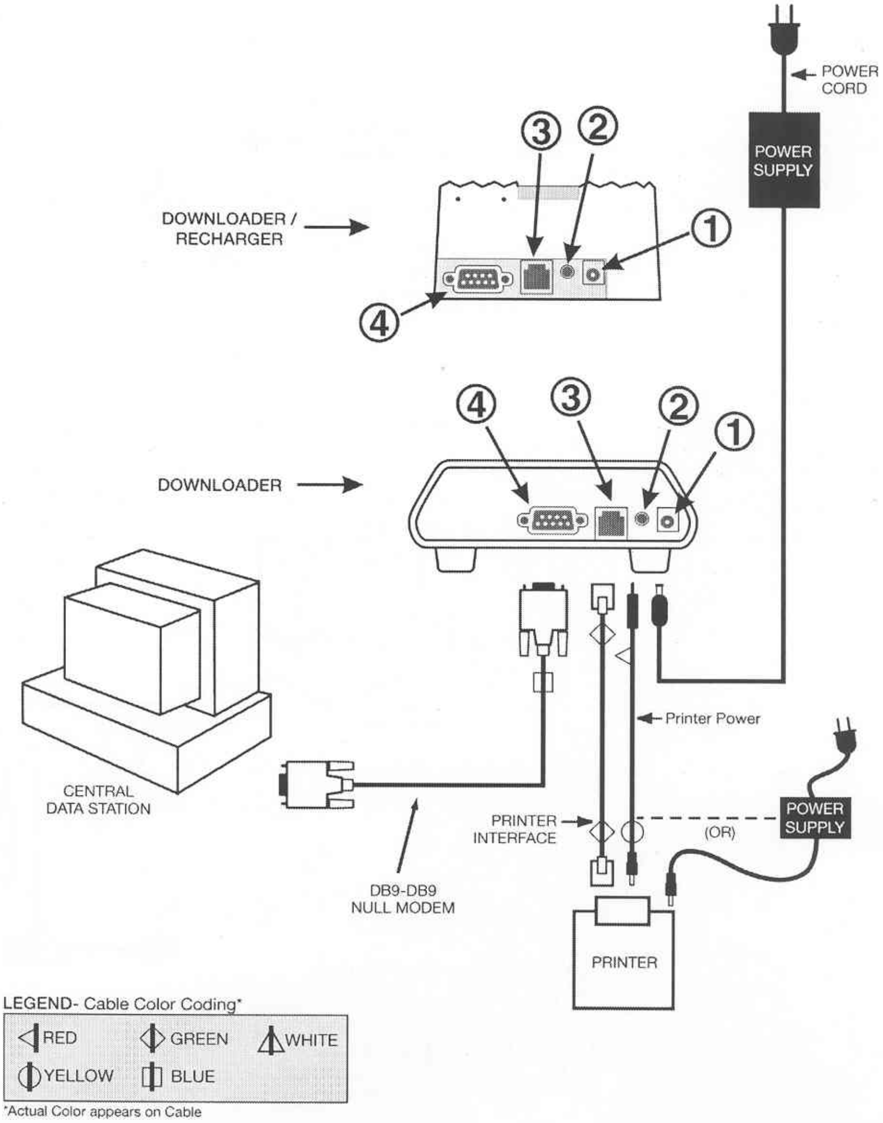
- DB9-DB9 Null Modem Cable
- Printer Interface Cable
- Printer Power Cable or Printer AC Adapter

① Power In

② Power Out

③ RJ12 (printer interface)

④ DB9


POWER CORD
POWER SUPPLY
③ ②
DOWNLOADER / RECHARGER
①
④
④ ③ ② ①
DOWNLOADER
Printer Power
CENTRAL DATA STATION
PRINTER INTERFACE
(OR)
POWER SUPPLY
DB9-DB9 NULL MODEM
PRINTER
LEGEND- Cable Color Coding*
RED
GREEN
WHITE
YELLOW
BLUE
*Actual Color appears on Cable

i-STAT®
TECHNICAL BULLETIN

ANALYZER CODED MESSAGES

From the time it powers up until the time it powers down, the i-STAT® Analyzer performs numerous quality checks. The failure of any quality check causes the analyzer to halt the test cycle and display a "cause", an "action" message, and a code.

The Cause Message:

This message describes the likely cause of the failed quality check. For example, when an overfilled cartridge is detected, the analyzer will display "Sample Positioned Beyond Fill Mark".

The Action Message:

This message indicates the appropriate action. For example, if it is likely the quality check will fail again the next time the analyzer is used, the instruction "Use Electronic Simulator" will be displayed. If the problem is related to an operator or cartridge, the instruction "Use Another Cartridge" will be displayed.

The Cause Code:

This is a numeric code associated with the failed quality check. Since multiple codes can be associated with a single cause message, this is essential information when contacting i-STAT Technical Services or your local support organization for further assistance. The codes are stored in the analyzer's memory along with other test records and are transmitted to the Central Data Station. The code list can be viewed and printed.

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the analyzer. These conditions are usually benign and go away after the next cartridge or Electronic Simulator is inserted, or after the offending condition is corrected.

Code Number	Cause/Action Message on Display	Explanation
1	**Dead Batteries** / Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargeable batteries. If you are experiencing this code frequently and use disposable batteries with the i-STAT 1 analyzer, you may want to consider the rechargeable battery system available with the i-STAT 1 Analyzer.

Abbott
Point of Care

Code Number	Cause/Action Message on Display	Explanation
2	**Temperature Out of Range** / Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Check the analyzer's temperature reading on the Status Page.
3	**New Software Installed** / Use Electronic Simulator	This message appears on the Portable Clinical Analyzer after new software has been installed or, in some cases, when a new customization profile is received.
4, 8	**Analyzer Interrupted** / Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in the analyzer. Batteries that are too short will not make proper contact. Check that the batteries are inserted properly and seated well in the analyzer; check the battery voltage on the analyzer's Status Page and replace batteries if low. NOTE: Patient results displayed before this code are valid.
5, 6, 9	**Analyzer Interrupted** / Ready for Use	The Portable Clinical Analyzer is unable to refresh the display. This can happen if power is interrupted before the analyzer powers itself down. Check that batteries are inserted properly and seated well in the analyzer. Batteries that are too short will not make proper contact. Check the battery voltage on the Status Page.
7	**Batteries Changed** / Ready for Use	This is a normal response on the Portable Clinical Analyzer when the batteries are changed after a code 1 has occurred.
10	**Temperature In Range** / Ready for Use	Temperature is back in range following a code 2 on the Portable Clinical Analyzer.
11	**Date Invalid** / Check Clock on Status Page	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check the date on the real time clock. The accuracy of the clock is checked at the beginning of a coagulation test. If the clock is inaccurate, Code 11 is triggered.
12	**Invalid or Expired CLEW** / See Manual	The CLEW standardization has expired. Download a valid CLEW. The date on the real time clock exceeds the expiration date of the CLEW software. Check the date on the real time clock.
13	**Invalid or Expired CLEW** / See Manual	The CLEW is corrupt or not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Download a valid CLEW. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization Profile to the latest version and re-transmit the profile to the analyzer.
14	**Analyzer Error** / See Manual	Customization profile is corrupted. Retransmit the customization profile. If code 14 reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
15	**Barcode Does Not Match Cartridge Type**	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	**Test Cancelled by Operator**	This message will appear in the stored test records on the i-STAT 1 Analyzer if the analyzer powers down before mandatory information was entered.

The following codes are associated with the cartridge or fluid movement within a cartridge. These conditions can be operator or sample related. In most cases, a new cartridge must be used. If a condition persists, especially if isolated to one analyzer, there may an analyzer problem.

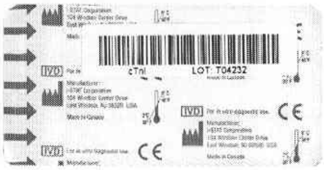
Code Number	Cause/Action Message on Display	Explanation
19	**No Clot Detetced** / See Manual	During the PT/INR cycle, no clot was detected. Run another cartridge. If code 19 reappears, run the sample on an alternate methodology.
22, 25	**Cartridge Error** / Use Another Cartridge	These codes occur only for coagulation cartridges if the mixing of the sample and reagent is compromised. This can be caused by an insufficient or clotted sample, or by air bubbles in the sample.
24	**Cartridge Error** / Use Another Cartridge	The electrical resistance of the calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. This could occur if the calibrant pack was ruptured well before the test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact i-STAT Technical Services or your local support organization.
26	**Cartridge Error** / Use Another Cartridge	This code occurs if there was a coagulation specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27-29, 32, 33, 40, 41, 45, 87	**Cartridge Error** / Use Another Cartridge	These codes identify problems with the cartridge such as: calibrant fluid arriving too soon, too late, or not at all, or noise in the calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact that can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin.
42, 43	**Cartridge Error** / Use Another Cartridge	These codes indicate that the conductometric sensor (code 42) or the amperometric sensor (code 43) was out of specification. This could be caused by a pre-burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer.
79-81	**Cartridge Error** / Use Another Cartridge	Bad contact between the thermal probes in the analyzer and the metalization on the back of the chips in the cartridge trigger these codes. Causes are: poor metalization of the chips, dirt on the metalization, or bent or broken thermal probes in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
21	**Cartridge Preburst** / Use Another Cartridge	This code indicates that the analyzer detected fluid on the sensors before it should have. Possible causes: mishandling of cartridges (putting pressure in the center of the cartridge), poor storage conditions of cartridges (frozen), or rerunning used cartridges.
31, 34, 44	**Unable to Position Sample** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
35, 36	**Sample Positioned Short of Fill Mark** / Use Another Cartridge	The cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.
30, 37	**Sample Positioned Beyond Fill Mark** / Use Another Cartridge	The cartridge was overfilled. The sample was past the fill mark. Try another cartridge.
38, 39	**Insufficient Sample** / Use Another Cartridge	This is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
46	**Cartridge Error** / Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample (especially in neonates), to not closing the snap closure on the cartridge, or to an aberrant cartridge.
47	**Cartridge Not Inserted Properly** / Reinsert Cartridge	This code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge or Electronic Simulator. If the problem persists and/or the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
48	**Analyzer Error** / See Manual	This code indicates the cartridge or Electronic Simulator may have been "cocked" when inserted. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain the cartridge or Simulator is properly inserted, it may indicate an analyzer problem. Contact i-STAT Technical Services or your local support organization for further assistance.
49	**Poor Contact Detected** / See Manual	The system detected a contact problem with one of the connector pins while reading the identification chip in the immunoassay cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1.

The following conditions are related to electronic or mechanical failures in the analyzer.

Code Number	Cause/Action Message on Display	Explanation
50	**Analyzer Error** / Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance. If testing immunoassay cartridges on an i-STAT 1 Analyzer, this code can be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	**Analyzer Error** / Use Electronic Simulator	The motor moved for too long. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
52	**Analyzer Error** / Use Electronic Simulator	The motor stalled while moving. Run a simulator. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue to use the analyzer. If the code reoccurs, contact i-STAT Technical Services or your local support organization for further assistance.
58-62	**Analyzer Error** / Use Electronic Simulator	The analyzer usually recovers from these error conditions. These error conditions can be detected by the Electronic Simulator. If the analyzer passes the Electronic Simulator test, continue to use it. If not, check the battery voltage and check the analyzer with another simulator to rule out a simulator problem. If the code persists, contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
23, 53, 55-57, 63, 65-68, 70, 72-74, 82, 85, 86, 89-94, 96, 97	**Analyzer Error** / See Manual	These are mechanical or electronic failures from which the analyzer may not be able to recover. Code 23 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. Code 70 can occur on the Portable Clinical Analyzer if the user presses the DIS key before the Electronic Simulator is run after a software update. If this happens, reseat the batteries to reset the analyzer, and then run the Electronic Simulator. Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzer. If these codes persist, contact i-STAT Technical Services or your local support organization for further assistance. Code 56 occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned. Code 86 can occur when an i-STAT Analyzer is stored in an i-STAT Downloader/Recharger without adequate ventilation. This problem can usually be resolved by moving the Downloader/Recharger to an open location which is free of obstructions and external heat sources such as heater vents or other electronic equipment. If this code persists, or if code 86 occurs with the Portable Clinical Analyzer or i-STAT 1 Analyzer without a Downloader/Recharger, contact i-STAT Technical Services or your local support organization for further assistance. For other codes, run the Electronic Simulator twice, then run a cartridge with a sample. If the analyzer passes the simulator check and a quality check does not occur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality code occurs with the sample run, contact i-STAT Technical Services or your local support organization for further assistance.

Code Number	Cause/Action Message on Display	Explanation
69	**Cartridge Type Not Recognized** / Use Another Cartridge	This code could be due to use of a cartridge type that is not compatible with the version of software in the analyzer, or the use of expired cartridges. Check the cartridge expiration date on the cartridge box or pouch. If the cartridges have not expired, and if a new cartridge type is being run, contact i-STAT Technical Services or your local support organization for a software update. When running coagulation cartridges, Code 69 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic cleaning cartridge. The specific conditioning procedure is described at the end of this bulletin. During immunoassay cartridge runs, this code will be displayed if incorrect information is entered in response to the prompt "Enter or Scan Cartridge Lot Number". The instrument expects the barcode on the back of the individual cartridge portion pack to be scanned. The correct barcode looks like this:  For immunoassay cartridges, the instrument will not accept keypad entries of the cartridge lot number nor a scan of the barcode on the cartridge box. This condition may be due to an aberrant cartridge. However, if the condition occurs repeatedly on one analyzer, the analyzer may need repair. Contact i-STAT Technical Services or your local support organization for further assistance.

Codes 100-111 indicate a condtion with the PCx or PCx Plus Glucose Test Strip on the i-STAT 1 Analyzer

Code Number	Cause/Action Message on Display	Explanation
100	**Strip Error** / Use Another Strip	The user tried to run a wet strip. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
101	**Strip Error** / Use Another Strip	The test strip was removed from the strip port during testing. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test.
103, 105, 106, 107, 111	**Strip Error** / Use Another Strip	Test unsuccessful. An error was detected during the analysis sequence. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test. If the problem persists, record the three digit error code and contact Abbott Diabetes Care support services or your local support organization.

Code Number	Cause/Action Message on Display	Explanation
102, 104	**Strip Error** / Use Another Strip	The test strip malfunctioned or the blood glucose level in the sample is beyond the measuring capability of the test strip and strip reader. Remove the test strip. Press 1 for Test Options. Press 1 for Same Patient or Level. Repeat the test with a new test strip. If the error occurs again, confirm the result by performing the test on a different method. Contact Abbott Diabetes Care support services or your local support organization.
108, 109	**Temperature Out of Range** / Check Status Page	During the test, room temperature became unstable or moved outside the limits within which the test strip reader can perform a test. Ensure that the room temperature is within the specified limits. Allow the analyzer to stabilize to a room temperature of 15-40°C or 59-104°F. Press the Menu key until the Administration Menu is displayed. Press 1 for Analyzer Status where the room temperature reading is displayed. If the temperature reading on the Status Page is within the limits described above, yet these codes persist, there may be a problem with one of the thermistors in the analyzer. Contact i-STAT Technical Services or your local support organization for further assistance.
110	**Strip Error** / Use Another Strip	At the start of the test strip cycle, the analyzer prompts the user to apply blood to the strip and waits for 20 minutes for the user to do so. This error occurs when the 20 minutes have elapsed and the analyzer didn't detect blood. The most likely cause of this error is lack of user interaction.

Codes in the range of 120 to 138 and 140 to 151 indicate a failure during an immuno cartridge cycle. In most cases, the cartridge is spent and another cartridge must be used. Only the i-STAT 1 Analyzer produces these codes, as the Portable Clinical Analyzer does not support immuno cycles.

Code Number	Cause/Action Message on Display	Explanation
120-122, 124, 125, 133, 144, 148	**Cartridge Error /** Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	**Cartridge Error /** Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. However, this code can also be related to poor electrical connection between the i-STAT 1 Analyzer and the cartridge. This can sometimes be corrected by conditioning the pins in the analyzer using the ceramic conditioning cartridge. The specific conditioning procedure is described at the end of this bulletin. **Note:** If you do not have a ceramic conditioning cartridge, please contact i-STAT Technical Support at 1-800-366-8020, option 1. Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for replacement.

Code Number	Cause/Action Message on Display	Explanation
127	**Cartridge Error /** Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.
128, 131, 132, 134, 135 - 138	**Cartridge Error /** Use Another Cartridge	These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles, or the abrupt insertion of a cartridge into the analyzer. **Guidelines for proper filling:** 1. **Discard** *(always)* 1 drop from delivery device to clear unseen bubbles. 2. **Hang** single drop slightly larger than round target well. 3. **Touch** one drop *(only)* to round target well allowing cartridge to draw sample in. 4. **Confirm** sample volume lines up with top of RED FILL LINE diagram. 5. **Close** slide cover from left to right. **Guidelines for cartridge insertion:** 1. After closing the cartridge, grasp the cartridge closure between your first finger and thumb. There is a recess for your thumb in the closure. 2. Guide the cartridge into the analyzer gently, until a soft click is heard.
129, 142, 143	**Cartridge Error /** Use Another Cartridge	The analyzer detected analysis fluid mixed with the sample. Try another cartridge.
130	**Cartridge Error /** Use Another Cartridge	The analyzer detected an air bubble in the sample segment. Try another cartridge.
140	**Lot Expired**	The analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.
141	**Test Canceled by Operator**	This code will be displayed if the cartridge barcode is not scanned within 60 seconds of cartridge insertion. The correct barcode to scan is the barcode on the cartridge portion pack, not the one on the cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above.
145	**Cartridge Error /** Use Another Cartridge	The analyzer failed to detect fluid arrival upon the initial sample push. This may be caused by a(n): • cartridge leak, • failure to close the cartridge completely. Ensure that the slide cover is fully engaged before inserting the cartridge into the analyzer • underfilled cartridge. Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the “fill to” mark, and then close the cartridge.
146	**Cartridge Error /** Use Another Cartridge	Overfilled cartridge. Repeat the test.

Code Number	Cause/Action Message on Display	Explanation
147	**Analyzer Error** / See Manual	In order to run an immunoassay cartridge, the i-STAT 1 Analyzer must: • bear the i immuno symbol and • be customized for a) Cartridge Barcode Required, or b) Cartridge Information First Required and Cartridge Lot Number Required. If either of these two conditions above are not met, the analyzer will display this code.
149 - 151	**Cartridge Error** / Use Another Cartridge	The analyzer detected an atypical data stream from the cartridge. Try another cartridge. For BNP, if code 150 is encountered when running a whole blood sample, it is recommended that the sample be centrifuged and the test be repeated with the resulting plasma.

The following conditions are related to the Electronic Simulator

Code	Explanation	How to Respond
Numerical Code	See under Analyzer Coded Messages.	See under Analyzer Coded Messages.
L	Potentiometric channel out of limits. Can occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Allow analyzer to equilibrate in new environment for 30 minutes and repeat test. If code reoccurs, return anlayzer.
G	Amperometric channel out of limits. Can occur if external simulator not inserted straight.	Reinsert the simulator straight. If code reoccurs, return analyzer.
R, r	Resistance reading on conductometric channel out of limits.	Return analyzer.
t	Thermal probe failure.	Return analyzer.
B	Potentiometric channel out of limits.	Return analyzer.

NOTE: Any time repetitive codes occur which cannot be addressed or corrected through training, contact i-STAT Technical Services or your local support organization for further assistance.

PROCEDURE FOR USING AN i-STAT CERAMIC CONDITIONING CARTRIDGE (CCC) FOR ANALYZER PIN CONDITIONING

Step Number	Explanation
1. Run an external Electronic Simulator.	If the analyzer is configured with the internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the internal Simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.
2. Run the CCC two times.	Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.
3. Update the CCC Usage Log	The log is located on page 3 of the Technical Bulletin entitled "Instructions for Restoring Analyzers That Produce *** for Hematocrit and Quality Check Code 23", which is shipped with the CCC. Updating the log allows the user to keep track of the number of pin conditioning cycles performed with the current ceramic strip in the CCC. If necessary, replace or rotate the ceramic strip so the CCC is ready for future use.
4. Return the analyzer to service.	

i-STAT®
TECHNICAL BULLETIN

Proficiency Testing on the i-STAT® System

Proficiency Testing for Non-Waived Tests (Moderate Complexity)

CLIA regulation *Subpart H – Participation in Proficiency Testing* requires a laboratory to enroll in a proficiency testing program approved by the Centers for Medicare and Medicaid Services (CMS) for its primary test system or that system used at its primary site. The laboratory must participate successfully as defined by the criteria defined in *Subpart I – Proficiency Testing Programs*.

A primary testing system is defined as the only method or the primary method for performing and reporting tests under a CLIA certificate. The i-STAT System may be a primary testing system when:

- A hospital has separate CLIA certificates for the main laboratory and point of care testing;
- A hospital owns a clinic, same-day surgery, kidney dialysis unit, etc., which requires a separate CLIA certificate;
- The i-STAT System is the hospital's primary laboratory testing system; or
- The i-STAT System is the main testing system in a physician's office, skilled nursing facility, unaffiliated patient transport service, homehealthcare agency, etc.

For CLIA regulated analytes, proficiency testing (PT) programs must provide three separate shipments during the year that include five challenges for each analyte or test. Laboratories must comply with the CLIA requirements and those of their accrediting organization when testing PT samples.

Proficiency Testing for Waived Tests

Proficiency Testing is not a CLIA requirement for waived tests. However, the College of American Pathologists (CAP) requires proficiency testing for waived tests. CMS, the Joint Commision and COLA do not require proficiency testing for waived tests. Check with your state regulatory agency for state requirements. Proficiency testing results for waived tests are not to be forwarded to CMS. Therefore, results from waived tests must be identified as such. Follow the Proficiency Testing survey providers' instructions for reporting waived test results.

The i-STAT System

It is recommended that the Proficiency Test path be used on the i-STAT Portable Clinical Analyzer and the i-STAT 1 Analyzer when testing proficiency samples that include hematocrit or ACT. The Proficiency Test path uses K_3EDTA standardization coefficients for hematocrit and disables the CPB mode. It also uses the PREWARM mode for ACT. Use of the Proficiency Test path will ensure that the results from analyzers customized for K_2EDTA, CPB-Always, or ACT NOWARM will match results from analyzers customized for K_3EDTA, CPB-Never and ACT PREWARM for survey reporting purposes. If the patient sample test path is

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used instead of the Proficiency Test path, do not select CPB, and if the analyzer is customized for K_2EDTA, divide the hematocrit results by 1.0425 before reporting. There is no reliable way of converting NONWARM ACT results to PREWARM ACT results.

- To access the Proficiency Test path on the Portable Clinical Analyzer:
  1. Insert the Electronic Simulator and wait for PASS to be displayed.
  2. Hold down the DIS key and press the MENU key to access the Utility menu.
  3. Press 5 for Proficiency.
- To access the Proficiency Test path on the i-STAT 1 Analyzer
  1. Press the On/Off key.
  2. Press the MENU key.
  3. Press 3 for Quality Tests.
  4. Press 2 for Proficiency.

PT Programs for the i-STAT System

In general, aqueous-based PT surveys are recommended for blood gas and electrolyte testing on the i-STAT System. Certain PT survey samples are not compatible with i-STAT System sensors and may contain interfering substances that could affect results. Fluorocarbon samples for blood gases and fixed-cell samples for hematocrit are not compatible with the sensors.

Occasionally, results from aqueous samples may differ between older and newer generations of cartridges. These differences may be significant. Abbott Point of Care will work with PT providers to prevent i-STAT System users from being unfairly penalized for PT failures that can be attributed to manufacturing changes. Note that the CLEW software prevents manufacturing changes from affecting results from blood samples.

Differences in pH, PCO_2 and hematocrit results between thermal and non-thermal cartridges can be expected for aqueous samples. (Thermal cartridges are temperature controlled at 37°C during the test cycle.) Some PT providers allow results to be coded as thermal or non-thermal. Others do not.

i-STAT Thermal Cartridges	i-STAT Non-Thermal Cartridges
CG4+	6+
CG8+	E3+
Crea	EC4+
EG6+	EC8+
EG7+	G
G3+	
CHEM8+	
PT/INR	
ACT Celite and ACT Kaolin	
cTnI	
CK-MB	
BNP	

Proficiency Testing Survey Providers

Note: This list may not include all providers and is not intended as an endorsement of any particular provider.

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
College of American Pathologists (CAP)			
College of American Pathologists (CAP) 325 Waukegan Road Northfield, IL 60093-2750 800-323-4040 or 847-832-7000 www.cap.org	CAP AQ and AQ2 surveys for blood gases and electrolytes LN13 Blood Gas/ Electrolytes/Cal Ver/ Linearity XL/XLN Excel Series Blood Gas/Electrolytes	*Instrument Codes:* *1927: i-STAT thermal cartridges.* *1928: i-STAT non-thermal cartridges.*	According to the AQ and AQ2 survey instructions, *P*O2 results should not be corrected for barometric pressure. **The barometric pressure should be reported with the uncorrected results.** Barometric pressure can be reported from the Status Page after the results are displayed.
	CAP CT1 and CAP EXCEL XC8 surveys for Activated Clotting Time (ACT)	*Instrument Code: i-STAT Kaolin ACT: 2058* *Instrument Code: i-STAT Celite ACT: 2085*	Samples are reconstituted with 0.025 mol/L (25 mmol/L) calcium chloride **supplied by the user.**
	CAP Plasma Cardiac Markers (PCARM) Survey XL/XLN Excel Series Troponin I Module L30	Instrument Code: 3277: i-STAT	For use with the i-STAT cTnI cartridges only.
	Whole Blood PT/INR (WP3)	N/A	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
American Association of Bioanalysts (AAB)			
American Association of Bioanalysts (AAB) AAB Proficiency Testing Service 205 West Levee St. Brownsville, Texas 78520 800-234-5315 www.aab.org	Activated Clotting Time	*Method Code: i-STAT Kaolin ACT: 600* *Method Code: i-STAT Celite ACT: 602*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Whole Blood Prothrombin Time	*Method Code: i-STAT PT/INR Cartridge: 600*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Basic Chemistry	*Instrument and Reagent Code: 145*	Use instrument and Reagent Code 154 for reporting CHEM8+ cartridge results
	Blood Gases	Method Codes: 145: i-STAT thermal cartridges. 146: i-STAT non-thermal cartridges.	
	Hematology (for Hct and Hb only)	Method Codes: 150: i-STAT thermal cartridges. 151: i-STAT non-thermal cartridges	

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
American Proficiency Institute (API)			
American Proficiency Institute (API) 1159 Business Park Drive Traverse City, MI 49686 800-333-0958 www.api-pt.com	i-STAT Chemistry (including Blood Gases) – Catalog #145	Method (Cartridges): • i-STAT thermal cartridges • i-STAT non-thermal cartridges	Indicate in the METHOD USED box whether the result is from a waived cartridge.
	i-STAT ACT (Activated Clotting Time) – Catalog #215	*Method (Cartridges):* • Celite ACT Cartridge • Kaolin ACT Cartridge	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	i-STAT Protime – Catalog #216	*N/A*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Plasma Cardiac Markers (PCM) - Catalog #157 (five samples) - Catalog #159 (two samples)	*N/A*	For use with i-STAT cTnI, CK-MB, and BNP cartridges.
WSLH PT			
Wisconsin State Laboratory of Hygiene (WSLH PT) 465 Henry Mall Room 402 Madison, WI 53706 800-462-5261 www.wslhpt.org	Activated Clotting Time (CTO)	*N/A.* See instructions for choosing the correct method information.	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Blood Gases/Electrolytes (BG) Blood Gases "Plus" for i-STAT (BP) Non-Blood Gas Analytes for i-STAT (NBG)	*N/A.* See instructions for choosing the correct method information.	
	i-STAT Protime/INR (PRC)	*N/A*	Samples are reconstituted with calcium chloride supplied by the Proficiency Provider.
	Cardiac Markers – 5 sample (IE) Cardiac Markers – 3 sample (TM)	N/A. See instructions for choosing the correct method information.	For use with i-STAT cTnI cartridges only. Survey CP is also compatible, but IE/TM is recommended for adequate i-STAT peer group statistics.
California Thoracic Society			
California Thoracic Society 202 Fashion Lane Suite 219 Tustin, CA 92780 714-730-1944 www.thoracic.org/chapters	Blood Gas / Electrolyte Survey (BG)	Method Codes for: • i-STAT Non-thermal Cartridges: 3676 • i-STAT Thermal Cartridges: 3677	

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
AccuTest Inc.			
AccuTest Inc. P.O. Box 999 7 Hayrick Lane Westford, MA 01886-0031 800-665-2575 www.digitalpt.com	Blood Gas / Electrolytes (BGAS435) and Blood Gas / Electrolytes POC (PBGA432)	N/A	For waived tests, use survey PBGA432
	Basic Chemistry (BCHE435)	N/A	For non-waived tests.
	Hematocrit (HCRT435) and Hematocrit POC (PHCR432) *(Hematocrit by conductivity methods survey only)*	N/A	For waived tests, use survey PHCR432
	Urea / Creatinine (URCR435) & Urea / Creatinine POC (PUCR432)	N/A	For waived tests, use survey PUCR432
HealthMetrx Canada Inc. (CANADA ONLY)			
HealthMetrx Canada Inc. (CANADA ONLY) 307-2083 Alma St. Vancouver, BC V6R 4N6 Canada 800-665-7436 www.digitalpt.com	Blood Gas / Electrolytes (BGAS435) and Blood Gas / Electrolytes POC (PBGA432)	N/A	
	Routine Chemistry (CHEM463)	N/A	
	Hematocrit (HCRT435) and Hematocrit POC (PHCR432) *(Hematocrit by conductivity methods survey only)*	N/A	
	Urea / Creatinine (URCR435) & Urea / Creatinine POC (PUCR432)	N/A	
New York State Department of Health			
New York State Department of Health Wadsworth Center P.O. Box 509 Albany, NY 12201-0509 518-485-5378 www.wadsworth.org	Blood pH and Gases	*i-STAT Instrument Code: IAA*	

Proficiency Provider	Survey Title(s)	Instrument and Method Codes	Additional Information or Recommendations
New York State Department of Health (cont.)	Clinical Chemistry	i-STAT Instrument Code: IAA Reagent Code: • i-STAT non-thermal cartridges: IA2 • i-STAT thermal cartridges: IA1	
American College of Physicians - Medical Laboratory Evaluation (MLE)			
Medical Laboratory Evaluation (MLE) 2011 Pennsylvania Avenue, NW Suite 800 Washington, DC 20006-1834 800-338-2746, option 5 www.acponline.org/mle email: mle@acponline.org	i-STAT Chemistry 1 - Catalog #817 (includes #818 & 847)	i-STAT Instrument Code 893 - Moderate Complexity Code 896 - Waived	Specimens are now liquid suspensions.
	i-STAT Chemistry 2 - Catalog #818	i-STAT Instrument Code 893 - Moderate Complexity Code 896 - Waived	Specimens are now liquid suspensions.
	Blood Gases - Catalog #847	Method Code: 893	
	i-STAT Protrombin Time - Catalog #328	i-STAT Instrument Code: 229	Samples are reconstituted with calcium chloride provided by the Proficiency survey provider.
American Academy of Family Physicians - Proficiency Testing Program (AAFP - PT)			
American Academy of Family Physicians Proficiency Testing Program (AAFP-PT) 11400 Tomahawk Creek Parkway Leawood, Kansas 66211-2672 800-274-7911 www.aafp.org/pt email: pt@aafp.org	Module 700 - i-STAT Chemistry	N/A	Includes sodium, potassium, chloride, BUN, creatinine, glucose, hemoglobin, hematocrit, TCO_2, ionized calcium and lactate.
	Module 702 - Blood Gases	N/A	Includes pH, $\mathbf{P}CO_2$, $\mathbf{P}O_2$, and iCa.
	Module 748 - i-STAT Protime	N/A	

i-STAT®
TECHNICAL BULLETIN

The i-STAT System and Waived Status

OVERVIEW

In September 2007, the FDA granted waived status for the i-STAT CHEM8+ cartridge. Waived status is applicable only when testing venous samples on the CHEM8+ cartridge using the i-STAT 1 Analyzer. The new test categorizations are listed on the CLIA database at http://www.fda.gov/cdrh/clia/.

Waived testing may be performed under all types of CLIA certificates: Certificate of Waiver (COW), Certificate of Provider-Performed Microscopy Procedures, Certificate of Compliance (COC), and a Certificate of Accreditation (COA). If you use only venous samples for testing and are maintaining a COC or COA in order to use the i-STAT CHEM8+ cartridge, you can “downgrade” to a COW the next time your Certificate is renewed.

THE i-STAT SYSTEM MANUAL FOR WAIVED TESTS

The i-STAT System Manual for Waived Tests is a scaled down version of the standard i-STAT 1 System Manual and is intended for facilities with a Certificate of Waiver. If you have a standard i-STAT 1 System Manual and are using the i-STAT System under a Certificate of Compliance (COC) or a Certificate of Accreditation (COA), it is not necessary to order the Waived Manual. This Technical Bulletin is intended as an update to the standard i-STAT 1 System Manual for the use of the waived cartridges.

While you do not need to have the Waived Manual if you maintain this Technical Bulletin in your current i-STAT 1 System Manual, you can order the i-STAT System Manual for Waived Tests (Abbott List Number 06F20-03) by contacting your Abbott Point of Care sales representative.

The Centers for Medicare and Medicaid Services (CMS), the Joint Commission, the College of American Pathologists (CAP), COLA and the American Osteopathic Association (AOA) will expect a facility to follow the instructions contained in the Waived Manual and summarized in this Technical Bulletin when using i-STAT waived cartridges to test venous samples. Facilities will be expected to follow the instructions in the standard i-STAT 1 Manual and the regulations for Moderate Complexity tests when using i-STAT waived cartridge to test other samples types.

PROFICIENCY TESTING

The Proficiency Testing Providers listed in the Technical Bulletin “Proficiency Testing on the i-STAT System,” have been informed about the CHEM8+ cartridge waived status. But it will take time for the providers to update their survey forms accordingly. Please contact your Proficiency Provider with any questions regarding the reporting of proficiency results from waived cartridges.

REQUIREMENTS FOR WAIVED TESTING VS MODERATE COMPLEXITY TESTING

The tables below summarize the differences in instructions described in the standard and waived i-STAT System Manuals and the major differences in the regulations for Moderate Complexity tests and Waived tests.

Note: Accrediting Organizations and certain States may have additional waived testing requirements including those regarding the laboratory director and personnel, policies and procedures, operator competency, specimen handling, results, control reporting and instrument maintenance. Some states may have their own lists of approved waived tests.

i-STAT System Instructions

Topic	Moderate Complexity Instructions	Waived Instructions
Electronic Simulator	Verify the performance of each analyzer using the Electronic Simulator (internal or external) once each day of use. The internal Electronic Simulator will automatically activate the first time a new or replacement analyzer is used and after every 24 hour period of use thereafter. The internal simulator can be customized to meet additional regulatory requirements.	The internal Electronic Simulator will automatically activate the first time a new or replacement Handheld is used and after every 24 hour period of use thereafter.
Liquid Quality Control	Check each newly received cartridge lot number with multiple levels of controls that test each sensor in use. (This is not a manufacturer's instruction but is necessary to comply with regulatory requirements.)	Check one CHEM8+ cartridge from each newly received lot with CHEM8+ Level 1 control.
Storage Temperature Monitoring	Verify that cartridges stored at room temperature are within the expiration date and that cartridges have not been out of the refrigerator for more than 14 days. Verify that the cartridges stored in the refrigerator are within the expiration date and that the storage refrigerator did not exceed the temperature limits of 2 to 8°C (35 to 46°F).	Verify that cartridges stored at room temperature are within the expiration date and that cartridges have not been out of the refrigerator for more than 14 days. Check refrigerated storage conditions monthly by testing one CHEM8+ cartridge with CHEM8+ Level 1 control. Test a cartridge on any analyzer.
Thermal Probe Check	Twice a year	Twice a year
Sample Type(s)	Venous, arterial and capillary samples are allowed according to the Sample Collection section and the Cartridge and Test Information sheets contained in the standard i-STAT 1 System Manual. When venous samples are used, the waived testing instructions must be followed.	**Venous only. If other sample types are tested, the instructions for Moderate Complexity testing MUST be followed.**

Overview of Regulatory Requirements

Regulatory Requirement	Moderate Complexity Cartridges and Waived Cartridges (with sample types other than Venous)	Waived Cartridges (with Venous Samples)
Performance Verification Validation	**Required For:** Accuracy, Precision, Reportable Range, Reference Range	**Not Required** (Reference range validation required for CAP)
Equivalent Quality Control (EQC) Validation	**Optional** (to reduce frequency of testing liquid controls)	**Not Required**
Liquid Quality Control	**Required**	**Not Required**
Proficiency Testing (PT)	**Required**	**Not Required** (PT required by CAP)
Calibration Verification	**Required**	**Not Required**
Comparison of Test Results	**Required**	**Not Required**

If both moderately complex and waived tests are performed in same unit/area, analyzers could be identified as "waived testing only" or "moderate complexity testing only" to make it easier to comply with the regulatory requirements.

i-STAT is a registered trademark of Abbott Laboratories.

MATERIAL SAFETY DATA SHEET FOR THE i-STAT AQUEOUS CONTROLS AND CALIBRATION VERIFICATION

In the following MSDS sheet from Bionostics, Inc, under Product Name, i-STAT CVC Levels are i-STAT Calibration Verification Levels. i-STAT Control Level 1 is equivalent to i-STAT Calibration Verification Level 2, i-STAT Control Level 2 is equivalent to i-STAT Calibration Verification Level 3 and i-STAT Control Level 3 is equivalent to i-STAT Calibration Verification Level 4.

i-STAT CHEM8+ Control Level 1 is equivalent to i-STAT CHEM8+ Calibration Verification Level 2, i-STAT CHEM8+ Control Level 2 is equivalent to i-STAT CHEM8+ Calibration Verification Level 3, i-STAT CHEM8+ Control Level 3 is equivalent to i-STAT CHEM8+ Calibration Verification Level 4.

The i-STAT CHEM8+ Calibration Verification Level 1b is used to verify the calibration of the i-STAT CHEM8+ TCO_2 at the low end of the reportable range.

Material Safety Data Sheet

According to 93/112/EC

Section I Chemical Product and Company Identification

Importer		Manufacturer	
Name:		Name:	Bionostics, Inc.
Address:		Address:	7 Jackson Road Devens, Massachusetts USA 01434
Telephone:		Telephone:	+01 978 772 7070
Fax:		Fax:	+01 978 772 7072

Product Name:	Catalog No:
i-STAT Control Levels 1, 2, and 3 i-STAT CVC Levels 1 through 5 CHEM8+ Control Levels 1, 2, and 3 CHEM8+ CVC Levels 1, 1B, 2, 3, 4, and 5	131000, 1315000, 132000, 135681, 01663101, 01663201, 01663301, 01663401, 01663501, 01663601, 01663701, 01422201, 01422301
Product Use: buffered aqueous solution for in vitro use for quality control of laboratory instrumentation	
Labeling Text N/A	Danger Symbol(s) N/A
Shipping Name N/A	IATA Not known

Section II Composition / Information on Ingredients

Chemical Family: salt solution		Chemical Name: N/A	
Component	CAS Number	Concentration Ranges	EEE Symbol / Risk Phrases

Contains no hazardous ingredients with concentration greater than 1% or carcinogens with concentration greater than 0.1%

Section III Hazards Identification

Eye Contact	May cause irritation if in contact with eye.
Skin Contact	Skin contact may cause irritation.
Ingestion	Though not a likely route of occupational exposure, ingestion of this product may cause choking, vomiting or nausea.
Inhalation	N/A
Chronic Exposure	N/A

Section IV First Aid Measures

Eye Contact	Although no adverse health reactions are expected from the normal use of this product, it is recommended flush eyes with water and seek medical advice whenever there has been a potential injury to the eye.
Skin Contact	If contact with this product leads to reddening, inflammation, or irritation, flush the exposed area with running water. If irritation persists, get medical attention.
Ingestion	As a precaution, get medical attention if there has been ingestion of this product.
Inhalation	If breathing becomes difficult, remove victim to fresh air. Get medical attention
Chronic Exposure	N/A

Section V Firefighting Measures

Autoflammability	not determined		
Flash Point (test method)	not determined		
Extinguishing Media	Use fire extinguishing media appropriate for site conditions.		
Special Firefighting Procedures	Structural fire fighting gear and self-contained breathing apparatus wil provide adequate protection if this product is in a fire area.		
Fire and Explosion Hazards	not determined		
Hazardous Combustion Products	Thermal decomposition may emit carbon monoxide and carbon dioxide.		
Upper Explosion Limit (%)	not determined	Lower Explosion Limit (%)	not determined

Section VI Accidental Release Measures

Spill and Leak Procedures	Use an absorbent material to contain/pick up the spilled solution. Place all contaminated disposables into a suitable container, seal, label and hold for disposal.

Section VII Handling and Storage

Storage Temperature	Store vials as directed in the package insert.
Handling / Storage	Handle and store vials as directed in the package insert.
Ventilation Requirements	No special requirements
Sensitivity to Static Electricity	not known
Sensitivity to Mechanical Impact	not known

Section VIII Exposure Controls / Personal Protection

Respiratory Protection	Respiratory protection is not required under normal use of this product.
Ventilation	Supplemental ventilation is not required for the normal use of this product.
Protective gloves	Protective gloves are not required for normal use of this product
Other Engineering controls	Eye wash stations and deluge showers.
Work Practices	Good laboratory technique should be used when handling this product. Observe appropriate chemical hygiene. Do not place in mouth.
Hygienic Practices	Do not eat, drink, or smoke while working with this product. Upon completion of work activities involving this product, wash hands thoroughly with soap and water.

Section IX Physical and Chemical Properties

Pure substance or preparation	Preparation	Physical Form	Liquid
Appearance / Odor	clear, odorless	pH AS is	neutral
Odor threshold	not determined	Boiling point (760 mmHg)	not determined
Melting / Freezing point	not determined	Solubility in Water	complete
Partition coefficient	not determined	Relative density	not determined
Evaporation rate	not determined	Vapor pressure (mmHg)	not determined
Vapor density (air = 1)	not determined	Viscosity	not determined
Volatiles	not determined	Volatile Organic Compounds	not determined
Autoflammability	not determined	Flash point	not determined
Oxidizing properties	not determined		

Section IX Physical and Chemical Properties

Stability	Stabile
Materials to avoid	Strong bases, strong acids and water reactive materials
Hazardous decomposition products	Thermal decomposition may emit carbon monoxide and carbon dioxide.

Section XI Toxicological Information

Route of Entry	Ingestion, skin and/or eye contact.		
Effects of chronic exposure	not known	Effects of acute exposure	not known
Special health effects	not known	Target organs	not known

Section XII Ecological Information

Potential effect on environment	not known	Potential to bioaccumulate	not known
Mobility	not known	Ecotoxicity	not known
Persistence and degradeability	not known	Aqua toxicity	not known

Section XIII Disposal Considerations

Waste disposal	Please consult local, state and federal regulations for additional guidance on disposal.
Empty container warnings	not known

Section XIV Transport Information (See also Section IX)

Not classified as hazardous for transport or dangerous goods

Section XV Regulatory Information

EEC hazard classification	not known
Risk phrases	not known
Safety phrases	not known

Section XVI Other Information

Directives 88/379/EEC and 91/155/EEC have been considered when compiling this SDS; the information is provided for health and safety assessment by an industrial user. Reference should be made to any relevant local or national health, safety or environmental legislation. This information does not constitute indication of suitability for specific uses.

The information, data and recommendations contained herein are based upon information believed by Bionostics, after reasonable investigation and research, to be accurate; however, Bionostics does not warrant the accuracy of this information. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals. Bionostics disclaims any warranty against patent infringement and the implied warranties of merchantability and fitness for a particular purpose. Customer's sole and exclusive remedy shall be replacement of the product or return of the product and refund of the purchase price, at Bionostics' option. In no case shall Bionostics be liable for incidental or consequential damages, including lost profits.

RNA®
MEDICAL

Material Safety Data Sheet

According to 93/112/EC

Section I Chemical Product and Company Identification

Importer		Manufacturer	
Name:		Name:	Bionostics, Inc.
Address:		Address:	7 Jackson Road Devens, Massachusetts USA 01434
Telephone:		Telephone:	+01 978 772 7070
Fax:		Fax:	+01 978 772 7072

Product Name: RNA Medical Hematocrit Control (for use with the i-STAT System)	Catalog No: 06F12-04, 06F12-05, 06F12-06
Product Use: buffered aqueous solution for in vitro use for quality control of laboratory instrumentation	
Labeling Text N/A	Danger Symbol(s) N/A
Shipping Name N/A	IATA Not known

Section II Composition / Information on Ingredients

Chemical Family: salt solution		Chemical Name: N/A	
Component	CAS Number	Concentration Ranges	EEE Symbol / Risk Phrases

Contains no hazardous ingredients with concentration greater than 1% or carcinogens with concentration greater than 0.1%

Section III Hazards Identification

Eye Contact	May cause irritation if in contact with eye.
Skin Contact	Skin contact may cause irritation.
Ingestion	Though not a likely route of occupational exposure, ingestion of this product may cause choking, vomiting or nausea.
Inhalation	N/A
Chronic Exposure	N/A

Section IV First Aid Measures

Eye Contact	Although no adverse health reactions are expected from the normal use of this product, it is recommended flush eyes with water and seek medical advice whenever there has been a potential injury to the eye.
Skin Contact	If contact with this product leads to reddening, inflammation, or irritation, flush the exposed area with running water. If irritation persists, get medical attention.
Ingestion	As a precaution, get medical attention if there has been ingestion of this product.
Inhalation	If breathing becomes difficult, remove victim to fresh air. Get medical attention
Chronic Exposure	N/A

Section V Firefighting Measures

Autoflammability	not determined		
Flash Point (test method)	not determined		
Extinguishing Media	Use fire extinguishing media appropriate for site conditions.		
Special Firefighting Procedures	Structural fire fighting gear and self-contained breathing apparatus wil provide adequate protection if this product is in a fire area.		
Fire and Explosion Hazards	not determined		
Hazardous Combustion Products	Thermal decomposition may emit carbon monoxide and carbon dioxide.		
Upper Explosion Limit (%)	not determined	Lower Explosion Limit (%)	not determined

Section VI Accidental Release Measures

Spill and Leak Procedures	Use an absorbent material to contain/pick up the spilled solution. Place all contaminated disposables into a suitable container, seal, label and hold for disposal.

Section VII Handling and Storage

Storage Temperature	Store vials as directed in the package insert.
Handling / Storage	Handle and store vials as directed in the package insert.
Ventilation Requirements	No special requirements
Sensitivity to Static Electricity	not known
Sensitivity to Mechanical Impact	not known

Section VIII Exposure Controls / Personal Protection

Respiratory Protection	Respiratory protection is not required under normal use of this product.
Ventilation	Supplemental ventilation is not required for the normal use of this product.
Protective gloves	Protective gloves are not required for normal use of this product
Other Engineering controls	Eye wash stations and deluge showers.
Work Practices	Good laboratory technique should be used when handling this product. Observe appropriate chemical hygiene. Do not place in mouth.
Hygienic Practices	Do not eat, drink, or smoke while working with this product. Upon completion of work activities involving this product, wash hands thoroughly with soap and water.

Section IX Physical and Chemical Properties

Pure substance or preparation	Preparation	Physical Form	Liquid
Appearance / Odor	clear, odorless	pH AS is	neutral
Odor threshold	not determined	Boiling point (760 mmHg)	not determined
Melting / Freezing point	not determined	Solubility in Water	complete
Partition coefficient	not determined	Relative density	not determined
Evaporation rate	not determined	Vapor pressure (mmHg)	not determined
Vapor density (air = 1)	not determined	Viscosity	not determined
Volatiles	not determined	Volatile Organic Compounds	not determined
Autoflammability	not determined	Flash point	not determined
Oxidizing properties	not determined		

Section IX Physical and Chemical Properties

Stability	Stabile
Materials to avoid	Strong bases, strong acids and water reactive materials
Hazardous decomposition products	Thermal decomposition may emit carbon monoxide and carbon dioxide.

Section XI Toxicological Information

Route of Entry	Ingestion, skin and/or eye contact.		
Effects of chronic exposure	not known	Effects of acute exposure	not known
Special health effects	not known	Target organs	not known

Section XII Ecological Information

Potential effect on environment	not known	Potential to bioaccumulate	not known
Mobility	not known	Ecotoxicity	not known
Persistence and degradeability	not known	Aqua toxicity	not known

Section XIII Disposal Considerations

Waste disposal	Please consult local, state and federal regulations for additional guidance on disposal.
Empty container warnings	not known

Section XIV Transport Information (See also Section IX)

Not classified as hazardous for transport or dangerous goods

Section XV Regulatory Information

EEC hazard classification	not known
Risk phrases	not known
Safety phrases	not known

Section XVI Other Information

Directives 88/379/EEC and 91/155/EEC have been considered when compiling this SDS; the information is provided for health and safety assessment by an industrial user. Reference should be made to any relevant local or national health, safety or environmental legislation. This information does not constitute indication of suitability for specific uses.

The information, data and recommendations contained herein are based upon information believed by Bionostics, after reasonable investigation and research, to be accurate; however, Bionostics does not warrant the accuracy of this information. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals. Bionostics disclaims any warranty against patent infringement and the implied warranties of merchantability and fitness for a particular purpose. Customer's sole and exclusive remedy shall be replacement of the product or return of the product and refund of the purchase price, at Bionostics' option. In no case shall Bionostics be liable for incidental or consequential damages, including lost profits.

RNA®
MEDICAL

Material Safety Data Sheet

According to 93/112/EC

Section I Chemical Product and Company Identification

Importer		Manufacturer	
Name:		Name:	Bionostics, Inc.
Address:		Address:	7 Jackson Road Devens, Massachusetts USA 01434
Telephone:		Telephone:	+01 978 772 7070
Fax:		Fax:	+01 978 772 7072

Product Name: RNA Medical Hematocrit Calibration Verification Controls for i-STAT	Catalog No: 06F12-07
Product Use: buffered aqueous solution for in vitro use for quality control of laboratory instrumentation	
Labeling Text N/A	Danger Symbol(s) N/A
Shipping Name N/A	IATA Not known

Section II Composition / Information on Ingredients

Chemical Family: salt solution		Chemical Name: N/A	
Component	CAS Number	Concentration Ranges	EEE Symbol / Risk Phrases

Contains no hazardous ingredients with concentration greater than 1% or carcinogens with concentration greater than 0.1%

Section III Hazards Identification

Eye Contact	May cause irritation if in contact with eye.
Skin Contact	Skin contact may cause irritation.
Ingestion	Though not a likely route of occupational exposure, ingestion of this product may cause choking, vomiting or nausea.
Inhalation	N/A
Chronic Exposure	N/A

Section IV First Aid Measures

Eye Contact	Although no adverse health reactions are expected from the normal use of this product, it is recommended flush eyes with water and seek medical advice whenever there has been a potential injury to the eye.
Skin Contact	If contact with this product leads to reddening, inflammation, or irritation, flush the exposed area with running water. If irritation persists, get medical attention.
Ingestion	As a precaution, get medical attention if there has been ingestion of this product.
Inhalation	If breathing becomes difficult, remove victim to fresh air. Get medical attention
Chronic Exposure	N/A

Section V Firefighting Measures

Autoflammability	not determined		
Flash Point (test method)	not determined		
Extinguishing Media	Use fire extinguishing media appropriate for site conditions.		
Special Firefighting Procedures	Structural fire fighting gear and self-contained breathing apparatus wil provide adequate protection if this product is in a fire area.		
Fire and Explosion Hazards	not determined		
Hazardous Combustion Products	Thermal decomposition may emit carbon monoxide and carbon dioxide.		
Upper Explosion Limit (%)	not determined	Lower Explosion Limit (%)	not determined

Section VI Accidental Release Measures

Spill and Leak Procedures	Use an absorbent material to contain/pick up the spilled solution. Place all contaminated disposables into a suitable container, seal, label and hold for disposal.

Section VII Handling and Storage

Storage Temperature	Store vials as directed in the package insert.
Handling / Storage	Handle and store vials as directed in the package insert.
Ventilation Requirements	No special requirements
Sensitivity to Static Electricity	not known
Sensitivity to Mechanical Impact	not known

Section VIII Exposure Controls / Personal Protection

Respiratory Protection	Respiratory protection is not required under normal use of this product.
Ventilation	Supplemental ventilation is not required for the normal use of this product.
Protective gloves	Protective gloves are not required for normal use of this product
Other Engineering controls	Eye wash stations and deluge showers.
Work Practices	Good laboratory technique should be used when handling this product. Observe appropriate chemical hygiene. Do not place in mouth.
Hygienic Practices	Do not eat, drink, or smoke while working with this product. Upon completion of work activities involving this product, wash hands thoroughly with soap and water.

Section IX Physical and Chemical Properties

Pure substance or preparation	Preparation	Physical Form	Liquid
Appearance / Odor	clear, odorless	pH AS is	neutral
Odor threshold	not determined	Boiling point (760 mmHg)	not determined
Melting / Freezing point	not determined	Solubility in Water	complete
Partition coefficient	not determined	Relative density	not determined
Evaporation rate	not determined	Vapor pressure (mmHg)	not determined
Vapor density (air = 1)	not determined	Viscosity	not determined
Volatiles	not determined	Volatile Organic Compounds	not determined
Autoflammability	not determined	Flash point	not determined
Oxidizing properties	not determined		

Section IX Physical and Chemical Properties

Stability	Stabile
Materials to avoid	Strong bases, strong acids and water reactive materials
Hazardous decomposition products	Thermal decomposition may emit carbon monoxide and carbon dioxide.

Section XI Toxicological Information

Route of Entry	Ingestion, skin and/or eye contact.		
Effects of chronic exposure	not known	Effects of acute exposure	not known
Special health effects	not known	Target organs	not known

Section XII Ecological Information

Potential effect on environment	not known	Potential to bioaccumulate	not known
Mobility	not known	Ecotoxicity	not known
Persistence and degradeability	not known	Aqua toxicity	not known

Section XIII Disposal Considerations

Waste disposal	Please consult local, state and federal regulations for additional guidance on disposal.
Empty container warnings	not known

Section XIV Transport Information (See also Section IX)

Not classified as hazardous for transport or dangerous goods

Section XV Regulatory Information

EEC hazard classification	not known
Risk phrases	not known
Safety phrases	not known

Section XVI Other Information

Directives 88/379/EEC and 91/155/EEC have been considered when compiling this SDS; the information is provided for health and safety assessment by an industrial user. Reference should be made to any relevant local or national health, safety or environmental legislation. This information does not constitute indication of suitability for specific uses.

The information, data and recommendations contained herein are based upon information believed by Bionostics, after reasonable investigation and research, to be accurate; however, Bionostics does not warrant the accuracy of this information. All materials and mixtures may present unknown hazards and should be used with caution. When necessary or appropriate, independent opinions regarding the risk of handling or exposure should be obtained from trained professionals. Bionostics disclaims any warranty against patent infringement and the implied warranties of merchantability and fitness for a particular purpose. Customer's sole and exclusive remedy shall be replacement of the product or return of the product and refund of the purchase price, at Bionostics' option. In no case shall Bionostics be liable for incidental or consequential damages, including lost profits.

PHOTOCOPY

TRINITY BIOTECH plc	**MSDS** NAME OF PRODUCT: i-STAT PT Normal Control and PT Abnormal Control Product Code: 50407/ 50408 MSDS Number: VA-0005
MATERIAL SAFETY DATA SHEET	**Effective date:** **Revision Number 00**

Written By: Nicola Flynn	**Date: 27 Jan 03**	**Approved by:**	**Date:** 27 Jn 03

1-PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: i-STAT PT Normal Control
i-STAT PT Abnormal Control

SUPPLIER:

Name:	Trinity Biotech Plc	**Emergency phone number:**	Contact national poisons unit.
Address:	IDA Business Park, Bray, Co. Wicklow, Ireland.		Ireland: 01-837 9964 Belgium (+31) 30 2748888 France (+331) 40.37.04.04 USA 1800-603 8076
Phone number:	+ 353 1 276 9800		
Fax number:	+ 353 1 276 9888		

2-COMPOSITION / INFORMATION ON COMPONENTS

PREPARATION/SUBSTANCE: Preparation
COMPONENTS CONTRIBUTING TO THE HAZARD:

The PT Normal and PT Abnormal Control Plasma Reagents consist of Human source plasma, that has been lyophilised. It does not contain any other hazardous ingredients.

3-HAZARD IDENTIFICATION

☣ **Biohazard**

WARNING STATEMENT

Each unit of human source plasma used in the preparation of this product has been tested by FDA approved methods for the presence of antibody to Human Immunodeficiency Virus (HIV) Type I and Type II, Hepatitis B surface antigen (HB_sAg) as well as for Hepatitis C (HCV) and found negative (not repeatedly reactive). Donors have been screened for Creutfeldt-Jakob Disease (CJD) and new variant Creutzfeldt-Jakob Disase (nvCJD) and found acceptable. However, no test can offer complete assurance that products derived from human blood will not transmit infectious disease. As with all materials of human origin, this product should be handled as a potentially infectious material. All wastes containing biological material should be properly labelled and stored separately from other wastes. Dispose of all waste materials according to prescribed international, national and local regulations. Direct or repeated contact may cause irritation. May cause sensitisation. For medical diagnostic use only.

4-FIRST-AID MEASURES

Eye and Skin Contact: Immediately flush/wash thoroughly with water for 15 minutes and notify medical personnel.
Inhalation: Not Applicable.
Ingestion: Drink a moderate amount (8-12 oz.) of water and immediately notify medical personnel.

5-FIRE-FIGHTING MEASURES

Extinguishing Media:
Use method suitable to surroundings (Eg: Water spray, Carbon dioxide, multipurpose dry chemical or halon-fire extinguisher).
Hazardous Combustion Products:

Not known.
Special Procedures:
Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6-ACCIDENTAL RELEASE MEASURES

Personal Precautions:
If material is released or spilled, take proper precautions to minimise exposure by using appropriate personal protective equipment. Shut off all sources of ignition.
Cleaning Methods:
Cordon off spill area and minimise the spreading of spilled material. Soak up material with absorbent. Wash spill area thoroughly with bleach: Tween (10:1) solution or other appropriate disinfectant.
Environmental Precautions:
Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations. Prevent runoff into sewers, storm drains, surface waters, and soil.

7-HANDLING AND STORAGE

Avoid contact with skin, eyes or clothing. Use adequate ventilation to minimise exposure. Wash thoroughly after handling. Store at 2-8°C.

8-EXPOSURE CONTROL / PERSONAL PROTECTION

Eye, Face and Skin Protection:
The choice of protection should be based on the job activity and potential for exposure to the eyes, face and skin. Wear safety glasses with side shields or full-face shield if eye contact is likely. Wear gloves, lab coat, or other protective overgarment if skin contact is likely.
Respiratory Protection:
When handling bulk quantities or for long durations where aerosolisation of material is likely or material may become airborne, wear a NIOSH/MSHA-approved air-purifying respirator.
Engineering Controls:
When practical, the material should be handled in enclosed or contained processes with a properly operating laboratory hood or with other effective local exhaust ventilation.
Hygiene Measures:
Wash hands immediately after handling this material (especially before eating, drinking or smoking). Decontaminate or discard protective equipment after each use. Should ingestion of the preparation occur, seek medical advice immediately.

9-PHYSICAL AND CHEMICAL PROPERTIES

This preparation consists of a lyophilised reagent (solid). Data is not currently available for the chemical properties of the preparation as a whole.

10-STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use. Hazardous polymerisation is not expected to occur.
Hazardous Decomposition Products: Unknown
Incompatibility: Unknown

11-TOXICOLOGICAL INFORMATION

Refer to Section 3 for Additional Information on Health Hazards

Each unit of human source plasma used in the preparation of this product has been tested by FDA approved methods for the presence of antibody to Human Immunodeficiency Virus (HIV) Type I and Type II, Hepatitis B surface antigen (HB_sAg) as well as for Hepatitis C (HCV) and found negative (not repeatedly reactive). Donors have been screened for Creutfeldt-Jakob Disease (CJD) and new variant Creutzfeldt-Jakob Disase (nvCJD) and found acceptable. However, no test can offer complete assurance that products derived from human blood will not transmit infectious disease. As with all materials of human origin, this product should be handled as a potentially infectious material. All wastes containing biological material should be properly labelled and stored separately from other wastes. Dispose of all waste materials according to prescribed international, national and local regulations.

12-ECOLOGICAL INFORMATION

No data available.

13-DISPOSAL CONSIDERATIONS

Incinerate or autoclave at 121°C/ 25°F for at least 90 minutes. All wastes containing the material should be properly labelled and stored separately from other waste. Dispose of waste materials according to prescribed national and local regulations.

14-TRANSPORT INFORMATION

Land Transport (ADR/RID): Not regulated.
Air Transport (ICAO/IATA): Not regulated.
Maritime Transport (IMO-IMDG): Not regulated.

15-REGULATORY INFORMATION

CAUTION- This preparation has not yet been fully tested.

16-OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it shall make their own determination of the effects, properties, and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material.

Corporate Office:

6025 Nicolle Street
Ventura, California 93003 USA
(805) 654-0643
Fax (805) 654-0681

biopool®
INTERNATIONAL

MATERIAL SAFETY DATA SHEET

PRODUCT COVERED:		Catalog #
Protein C Normal Control		40112
Factor II, VII and X Deficient Plasma		40192
Protein S Normal Control		40225
Factor II Deficient Plasma		40702
Factor V Immunodepleted Plasma		40705
Antithrombin III Deficient Plasma		40706
Factor VII Immunodepleted Plasma		40707
Factor VIII Immunodepleted Plasma		40708
Factor IX Immunodepleted Plasma		40709
Factor X Immunodepleted Plasma		40710
Factor XI Deficient Plasma		40711
Factor XII Deficient Plasma		40712
Protein C Deficient Plasma		40723
Protein C Abnormal Control		40724
Protein S Deficient Plasma		40815
Factor II Deficient Plasma (immunedepleted)		50002
Factor V Deficient Plasma (congenital)		50005
Factor VII Deficient Plasma (congenital)		50007
Factor VIII Deficient Plasma (congenital)		50008
Factor IX Deficient Plasma (congenital)		50009
Factor X Deficient Plasma (congenital)		50010
Fletcher Factor Deficient Plasma		50013
von Willebrand Deficient Plasma		50014
Normal Coagulation Control Plasma (NCCP)	i-STAT ACT Controls	50100
Abnormal Coagulation Control Plasma-1 (ACCP-1)		50101
Abnormal Coagulation Control Plasma-2 (ACCP-2)		50102
Coagulation Reference Plasma, Abnormal (CRP, Abnormal		50106
Low Fibrinogen Control Plasma		50107
Abnormal Reference Plasma-VIII (ARP-VIII)		50108
Abnormal Reference Plasma-IX (ARP-IX)		50109
Low Heparin Control Plasma		50111
High Heparin Control Plasma		50112
LA Positive Control Plasma (Human), 1.0 mL		50113
LA Positive.Control Plasma (Human), 0.5 mL		50114
Platelets, Lyophilized		50710
Platelets, Lyophilized		50711
Hemostasis Reference Plasma		50720
Hemostasis Reference Plasma, Abnormal		50721

HAZARDOUS INGREDIENTS

HUMAN PLASMA

PHYSICAL DATA:	Not applicable.
FIRE AND EXPLOSION HAZARD DATA:	Not considered to be a fire and explosion hazard.
HEALTH HAZARD DATA:	Handle these components as POTENTIALLY BIOHAZARDOUS materials. The plasma used in the preparation of this product has been tested and found negative for HIV and HB$_s$Ag by FDA approved methods. However, no test can offer complete assurance that products derived from human blood will not transmit infectious disease. As with all materials of human origin, products should be handled as potentially infectious material.
PROTECTIVE MEASURES:	Do not pipet any solution by mouth. Do not eat, drink, smoke, or apply cosmetics in the laboratory. Avoid direct contact by using proper protective articles; i.e., closed toe shoes, lab coats, gloves, etc.
EMERGENCY AND FIRST AID PROCEDURES:	Eye Exposure: Flush with water for at least 15 minutes. Skin Exposure: Wash well with soap and water. If skin is broken or material enters an open wound, get medical attention. Ingestion: Flush mouth with water, without swallowing. Get medical attention.
SPILL AND DISPOSAL PROCEDURES:	Don protective gear. Carefully wipe up spills with absorbent paper and thoroughly cleanse area with a strong disinfectant. Dispose of all cleaning materials, spent pipet tips, containers, and unused reagents in accordance with Federal, State, and Local regulations.
STORAGE:	Store products at 2° - 8° C.

The information contained in this Material Safety Data Listing is believed, but not warranted, to be accurate. The user should determine the suitability of the information presented and adopt appropriate safety precautions.

Rev. 01/97

Material Safety Data Sheet

Manufacturer's Name	**HEMATRONIX, INC.**	**Product Name** **METER TRAX**
Manufacturer's Address **City, State, Zip**	524 Stone Rd., Suite A Benicia, CA 94510	**Emergency Phone Number** (707) 746-7833

I. Product Identification	
A. Trade Name	**METER TRAX**
B. Synonym(s)	Whole Blood Reference Control for Glucose, Hemoglobin and Hematocrit

II. Hazardous Ingredients

Component	**%**	**Nature of Hazard**
Human Blood	98	Handle as potentially infectious. The human constituents, however, have tested negative for antibodies to Human Immunodeficiency Virus (HIV), Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (HCV).

III. Physical Data	
A. Appearance	Dark red
B. Odor	N/A
C. Boiling Point	N/A
D. Evaporation Rate	N/A
E. Specific Gravity	N/A
F. Percent Volatile	N/A
G. Vapor Density	N/A
H. Vapor Pressure	N/A
I. Water Solubility	N/A

IV. Fire and Explosion Information

A. Flash Point	Non-flammable
B. Fire Extinguishing Media	Carbon dioxide, dry chemical powder, alcohol or polymer foam, water spray
C. Fire Fighting Procedures	Cool fire-exposed containers with water spray.
D. Explosion Hazards	None
E. Special Information	Wear protective clothing to protect skin and eyes.

V. Health Hazards

A. Thresholds Limit Value	Unknown
B. Routes of Exposure	
1. Ingestion	See #D below: Emergency and First Aid Procedures.
2. Inhalation	None
3. Skin Contact	See #D below: Emergency and First Aid Procedures.
4. Skin Absorption	See #D below: Emergency and First Aid Procedures.
5. Eye Contact	See #D below: Emergency and First Aid Procedures.

Effective Date: November 5, 1998 **Supercedes: September 20, 1996**

Manufacturer's Name	**HEMATRONIX, INC.**	**Product Name** **METER TRAX**
Manufacturer's Address **City, State, Zip**	524 Stone Rd., Suite A Benicia, CA 94510	**Emergency Phone Number** (707) 746-7833

C. Effects of Overexposure	
1. Acute Overexposure	None
2. Chronic Overexposure	None
D. Emergency and First Aid Procedures	
1. Ingestion	Contact a physician for prophylatic treatment.
2. Inhalation	None
3. Skin Contact	Wash affected area with water and a germicidal agent. Contact a physician.
4. Eye Contact	Flush with copious amounts of water. Contact a physician for further treatment.
E. Aggravation of Pre-existing Conditions	None

VI. Reactivity	
A. Stability – Conditions to Avoid	Stable product
B. Incompatibilities	N/A
C. Hazardous Decomposition Products	None

VII. Spill/Leak and Disposal Procedures	
A. Spills	Neutralize spill by treatment with a 1:10 dilution of sodium hypochlorite (bleach) solution. Allow to stand 5-10 minutes. Using gloves and a mask, if necessary, wipe up all spilled and excess material, and dispose in a biohazardous waste container.
B. Disposal	If available, incinerate, or autoclave before disposal. Otherwise, place in a clearly marked biohazardous container and dispose per local, state, and federal regulations.

VIII. Protective Information (Occupational Control Measures)	
A. Airborne Exposure Limits	None
B. Respiratory Protective Information	None
C. Ventilation System	Routine exhaust ventilation
D. Protective Equipment	
1. Skin Protection	Wear gloves
2. Eye Protection	Wear goggles if spills or splashes pose a threat

IX. Handling and Storage: Special Precautions
Store at 2° – 8° C (35° - 46°F). Do not freeze.

X. Miscellaneous Information

Effective Date: November 5, 1998 **Supercedes: September 20, 1996**

MATERIAL SAFETY DATA SHEET

MSDS009

Ultralife Batteries, Inc.
2000 Technology Parkway
Newark, NY 14513-2175

Emergency Telephone Number:
Chemtrec for Spills, Leaks, Fires
USA 1-800-424-9300
International 703-527-3887

SECTION I PRODUCT IDENTIFICATION

Product Name:	Ultralife Lithium Power Cell
Size:	U9VL and U3VL
Chemistry System:	Manganese Dioxide/Lithium Metal

SECTION II PRECAUTIONARY LABELING

Caution: May leak and/or flame if opened, recharged, connected improperly, or disposed of in fire.

SECTION III HAZARDOUS COMPONENTS

	Approximate percent of total weight
Manganese Dioxide	12.0 – 15.0
Lithium Metal	2.0 – 3.0
Electrolyte containing:	
Organic solvents	13.0 – 15.0
Lithium Hexafluoroarsenate	2.0 – 3.0

SECTION IV FIRE AND EXPLOSION DATA

A. Extinguishing Media

- A copious amount of cold water is an effective extinguishing medium for lithium batteries. Do not use warm or hot water.
- Lith-X (Class D extinguishing media) is effective on fires involving only a few cells.
- Do not use CO_2 or Halon type extinguishing media.
- Dry Chemical type extinguishers have limited extinguishing potential.

B. Fire Fighting Procedures

- Use a positive pressure self-contained breathing apparatus if batteries are involved in a fire.
- Full protective clothing is necessary.
- During water application, caution is advised as burning pieces of lithium may be ejected from the fire.

C. Unusual Fire and Explosion Hazards

- Batteries may flame or leak potentially hazardous organic vapors if exposed to excessive heat or fire.
- Fire or excessive heat may produce hazardous decomposition products.
- Damaged or opened batteries can result in rapid heating and the release of flammable vapors. Vapors are heavier than air and may travel along the ground or be moved by ventilation to an ignition source and flash back.

SECTION V STORAGE PRECAUTIONS

- Do not store batteries in a manner that allows terminals to short circuit.
- Store batteries in a cool (below 70°F), dry area that is subject to little temperature change.
- Do not place near heating equipment, nor expose to direct sunlight for long periods. Elevated temperatures can result in reduced battery service life.

SECTION VI HANDLING/ USE PRECAUTIONS

A. Battery Charging

- Batteries are not designed to be recharged. Charging a battery may result in electrolyte leakage and/ or cause the battery to flame.

B. Battery Disassembly

- Never disassemble a battery.
- Should a battery unintentionally be crushed, thus releasing its contents, rubber gloves must be used to handle all battery components. Avoid inhalation of any vapors that may be emitted.
- In the event of skin or eye exposure to the electrolyte, refer to Section VII, First Aid Information.

C. Battery Short Circuit

- More than a momentary short circuit will generally reduce the battery service life.
- Extended short circuiting creates high temperatures in the cell. High temperatures can cause burns in skin or cause the cell to flame.
- Avoid reversing battery polarity within the battery assembly. To do so may cause cell to flame or to leak.

- The use of old and new batteries or batteries of varying sizes and types in the same battery assembly should be avoided. The batteries electrical characteristics and capabilities vary and damage may result to batteries or electrical equipment.

SECTION VII FIRST AID INFORMATION

A. Electrolyte Contact

- Skin- Immediately flush with plenty of water for at least 15 minutes. If symptoms are present after flushing, get medical attention.
- Eyes- Immediately flush with plenty of water for at least 15 minutes and get medical attention.

B. Lithium Metal Contact

- Skin- Remove particles of lithium from skin as rapidly as possible. Immediately flush with plenty of water for at least 15 minutes and get medical attention.
- Eyes- Immediately flush with plenty of water for at least 15 minutes and get immediate medical attention.

SECTION VIII DISPOSAL PROCEDURES

- Batteries must be completely discharged prior to disposal and/ or the terminals must be taped or capped to prevent short circuit.
- Disposal of large quantities of lithium power cells may be subject to Federal, State, or Local regulations.

SECTION IX TRANSPORTATION

- Shipment of the Ultralife Lithium Power Cell is governed by U.S. Department of Transportation 49 CFR 173.185 (i). Ultralife Lithium Power Cells are in compliance with this paragraph and therefore may be shipped as non-hazardous material.

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The information contained herein is furnished without warranty of any kind. Users should consider this data only as a supplement to other information gathered by them and must make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.

MATERIAL SAFETY DATA SHEET

Harding Energy Systems, Inc.
One Energy Centre
Norton Shores, MI 49441

Information Telephone No.:
(231) 798-7033

Date of Preparation: August 13, 1999

Section I – Product Identification

Product Name: Nickel Metal Hydride Battery

Trade Name: Quest

Nominal Voltage: 1.2V

Chemical System: Nickel Metal Hydride-AB5

Designated for Recharge:
_X_ Yes __ No

Section II – Hazardous Ingredients

IMPORTANT NOTICE: The product is a manufactured article. The battery cell is contained in a hermetically sealed case, designed to withstand the temperatures and pressures encountered during normal use. As a result, during normal use, hazardous materials are fully contained inside the battery cell. The battery cell should not be opened or exposed to heat because exposure to the following ingredients contained within could be harmful under some circumstances. The following information is provided for the user's convenience only.

Chemical Name	Cas. No.	OSHA PEL (mg/m^3)	ACGIH TLV (mg/m^3)
Nickel (powder)	7440-02-0	1TWA	1TWA
Nickel hydroxide	12054-48-7	1 TWA	1TWA
Cobalt	7440-48-4	0.1TWA	Dust & Fume: 0.05
Manganese	7439-96-5	Fume: 5 Ceiling Limit	Dust: 5 Fume: 1
Lanthanum	7439-91-0	NA	NA
Cerium	7440-45-1	NA	NA
Neodymium	7440-00-8	NA	NA
Potassium hydroxide	1310-58-3	NA	2Ceiling Limit
Sodium hydroxide	1310-73-2	2TWA	2 Ceiling Limit
Lithium hydroxide	1310-65-2	NA	NA

Notes: 1. Concentrations vary depending on the state of charge or discharge.
2. TWA is the time weighted average concentration over an 8-hour period.

Section III – Physical Data for Battery

Melting Point (°F) N/A	Boiling Point (°F) N/A	% Volatile by Volume N/A
Vapor Pressure (mm Hg) N/A	Evaporation Rate N/A	Vapor Density (Air = 1) N/A
Specific Gravity (H_2O) N/A	Solubility in Water N/A	Appearance and Odor No Odor

Section IV – Fire and Explosion Hazard Data

Flash Point: NA Lower Explosive Limit: NA Upper Explosive Limit: NA

Extinguishing Media: Any class of extinguishing medium may be used on the batteries or their packing material.

Special Fire Fighting Procedures: Exposure to temperatures above 212° F can cause venting of the liquid electrolyte. Internal shorting could also cause venting of the electrolyte. Potential for exposure to iron, nickel, cobalt, rare earth metals (cerium, lanthanum, neodymium, and praseodymium), manganese, and aluminum fumes during fire; use Self-Contained Breathing Apparatus.

Section V – Health Hazard Data

Threshold Limit Values: See Section II.

Effects of a Single (Acute) Overexposure

Inhalation: During normal use inhalation is an unlikely route of exposure due to containment of hazardous materials within the battery case. However, should the batteries be exposed to extreme heat or pressures causing a breach in the battery cell case, exposure to the constituents may occur. Inhalation of cobalt dusts may result in pulmonary conditions.

Ingestion: If the battery case is breached in the digestive tract, the electrolyte may cause localized burns.

Skin Absorption: No evidence of adverse effects from available data.

Skin Contact: Exposure to the electrolyte contained inside the battery may result in a chemical burn. Exposure to nickel may cause dermatitis in some sensitive individuals.

Eye Contact: Exposure to the electrolyte contained inside the battery may result in severe irritation and chemical burns.

Carcinogens:

Nickel has been identified by the National Toxicology Program (NTP) as reasonably anticipated to be a carcinogen. Cobalt has been identified by IARC as a 2B carcinogen.

Other Effects of Repeated (Chronic) Exposure

Chronic overexposure to nickel may result in cancer; dermal contact may result in dermatitis in sensitive individuals.

Medical Conditions Aggravated by Overexposure

A knowledge of the available toxicology information and of the physical and chemical properties of the material suggest that overexposure is unlikely to aggravate existing medical conditions.

Emergency and First Aid Procedures

Swallowing: Do not induce vomiting. Seek medical attention immediately.

Skin: If the internal cell materials of an opened battery cell comes into contact with the skin, immediately flush with water for at least 15 minutes.

Inhalation: If potential for exposure to fumes or dust occurs, remove immediately to fresh air and seek medical attention.

Eyes: If the contents from an opened battery comes into contact with the eyes, immediately flush eyes with water continuously for at least 15 minutes. Seek medical attention.

Section VI – Reactivity Data

The batteries are stable under normal operating conditions.

Hazardous polymerization will not occur.

Hazardous decomposition products: oxides of nickel, manganese, lanthanum, and cerium.

Conditions to avoid: heat, open flames, sparks, and moisture.

Potential incompatibilities (i.e., materials to avoid contact with): The battery cells are encased in a non-reactive container; however, if the container is breached, avoid contact of internal battery components with acids, aldehydes, and carbonate compounds.

Section VII – Spill and Leak Procedures

Spills and leaks are unlikely because cells are contained in a hermetically-sealed case. If the battery case is breached, don protective clothing that is impervious to caustic materials and absorb or pack spill residues in inert material. Dispose in accordance with applicable state and federal regulations.

Section VIII – Safe Handling and Use (Personal Protective Equipment)

Ventilation Requirements: Not required under normal use.

Respiratory Protection: Not required under normal use.

Eye Protection: Not required under normal use.

Gloves: Not required under normal use.

Section IX – Precautions for Safe Handling and Use

Storage: Store in a cool place, but prevent condensation on cell or battery terminals. Elevated temperatures may result in reduced battery life. Optimum storage temperatures are between –31°F and 95°F.

Mechanical Containment: If there are special encapsulation or sealing requirements, consult the Harding Energy, Inc. Engineering Dept. about possible cell hazard precautions or limitations.

Handling: Accidental short circuit will bring high temperature elevation to the battery as well as shorten the battery life. Be sure to avoid prolonged short circuit since the heat can burn attendant skin and even rupture of the battery cell case. Battery shrink wrap, labels, and insulators should be left intact in order to minimize the chance of short circuiting. Batteries packaged in bulk containers should have labels along the entire of their can, or they should be separated by dividers. Metal covered tables or belts used for assembly of batteries into devices can be the source of short circuits; apply insulating material to assembly work surface.

If soldering or welding to the case of the battery is required, consult the Harding Energy, Inc. Engineering Dept. for proper precautions to prevent seal damage or external short circuit.

Charging: This battery is designed for recharging. A loss of voltage and capacity of batteries due to self-discharge during prolonged storage is unavoidable. Charge battery before use. Observe the specified charge rate since higher rates can cause a rise in internal gas pressure which may result in damaging heat generation or cell rupture and or venting.

Labeling: If normal label warnings are not visible, it is important to provide a device label stating:

> CAUTION: Do not dispose in fire, mix with other battery types, charge above specified rate; connect improperly, or short circuit, which may result in overheating, explosion or leakage of cell contents.

Disposal: Dispose in accordance with all applicable state and federal laws and regulations.

DO NOT INCINERATE or subject battery cells to temperatures in excess of 212° F. Such treatment can cause cell rupture.

Section XIV – Transportation

U.S. DOT Information
- Basic Description: NON HAZARDOUS MATERIAL
- Proper Shipping Name: N/A
- Hazardous Class: N/A
- Packaging Group: N/A
- UN Number: N/A
- Limitations: N/A

IATA
- Proper Shipping Name: NON HAZARDOUS MATERIAL
- Hazard Class: N/A
- Packing Group: N/A
- UN Number: N/A
- Limitations: N/A

IMO

Proper Shipping Name: NON HAZARDOUS MATERIAL
Class: N/A
UN Number: N/A
Packing Group: N/A
EMS: N/A
MFAG: N/A
Marine Pollutant: N/A
Canadian TDG: N/A

The information and recommendations set forth are made in good faith and believed to be accurate as of the date of preparation. Harding Energy, Inc. makes no warranty, expressed or implied, with respect to this information and disclaims all liabilities from reliance on it.

Material Safety Data Sheets

TEIG NICKEL METAL HYDRIDE BATTERY

Section 1 - Product and Company Identification
TEIG NICKEL METAL HYDRIDE BATTERY

Product Identification: TEIG NICKEL METAL HYDRIDE BATTERY
Date of MSDS: 08/10/2002 **Technical Review Date:** 12/17/2002
Trade Name: TEIG
Chemical System: Nickel Metal Hydride
Nominal Voltage: 1.2V
Designated for Recharge: Y

Manufacturer's Information

Manufacturer's Name: AMERICAN TOPPOWER
Manufacturer's Address1: 2003 ROUTE 130 UNIT N
Manufacturer's Address2: MONMOUTH JUNCTION, NJ 08852
Manufacturer's Country: U.S.A
General Information Telephone: 732-821-1000 9 am~4:30 pm
Emergency Telephone: 732-821-1000 9 am~4:30 pm

Section 2 - Composition/Information on Ingredients
TEIG NICKEL METAL HYDRIDE BATTERY

CAS: 7440-02-0 **RTECS #:** QR5950000
Name: NICKEL (POWDER)
% low Wt: 3. **Code:** M **% high Wt:** 30. **Code:** M
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: 1 MG/M3 **Code:** T **OSHA STEL:** N/P **Code:**
ACGIH TLV: 1 MG/M3 **Code:** T **ACGIH STEL:** Not Established **Code:** T
EPA Rpt Qty: 100 LBS **DOT Rpt Qty:** 100 LBS
Ozone Depleting Chemical: N

CAS: 12054-48-7 **RTECS #:** QR7040000
Name: NICKEL HYDROXIDE
% low Wt: 17. **Code:** M **% high Wt:** 30. **Code:** M
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: 1 MG/M3 **Code:** T **OSHA STEL:** N/P **Code:**
ACGIH TLV: 1 MG/M3 **Code:** T **ACGIH STEL:** Not Established **Code:** T
EPA Rpt Qty: 10 LBS **DOT Rpt Qty:** 10 LBS

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Ozone Depleting Chemical: N

CAS Number: 7440-45-1 **RTECS Code:** X
Name: **CERIUM**
% low Wt: **Code:** **% high Wt:** **Code:**
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: Not established **Code:** M **OSHA STEL:** N/P **Code:**
ACGIH TLV: Not established **Code:** M **ACGIH STEL:** N/P **Code:**
EPA Rpt Qty: **DOT Rpt Qty:**
Ozone Depleting Chemical: N

CAS: 7439-91-0 **RTECS #:** X
Name: **LANTHANUM**
% low Wt: **Code:** **% high Wt:** **Code:**
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: Not established **Code:** M **OSHA STEL:** N/P **Code:**
ACGIH TLV: Not established **Code:** M **ACGIH STEL:** Not Established **Code:**
EPA Rpt Qty: **DOT Rpt Qty:**
Ozone Depleting Chemical: N

CAS: 1310-65-2 **RTECS #:** OJ6307070
Name: **LITHIUM HYDROXIDE**
% low Wt: **Code:** **% high Wt:** **Code:**
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: Not established **Code:** M **OSHA STEL:** N/P **Code:**
ACGIH TLV: Not established **Code:** M **ACGIH STEL:** Not Established **Code:**
EPA Rpt Qty: **DOT Rpt Qty:**
Ozone Depleting Chemical: N

CAS: 7440-00-8 **RTECS #:** QO8575000
Name: **NEODYMIUM**
% low Wt: **Code:** **% high Wt:** **Code:**
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: Not established **Code:** M **OSHA STEL:** N/P **Code:**
ACGIH TLV: Not established **Code:** M **ACGIH STEL:** Not Established **Code:**
EPA Rpt Qty: **DOT Rpt Qty:**
Ozone Depleting Chemical: N

CAS: 7440-48-4 **RTECS #:** GF8750000
Name: **COBALT (COBALT AND COBALT HYDROXIDE)**
% low Wt: 1. **Code:** M **% high Wt:** 2. **Code:** M
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: 0.1 MG/M3 **Code:** T **OSHA STEL:** N/P **Code:**

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ACGIH TLV: 0.02 MG/M3 **Code:** T **ACGIH STEL:** Not Established **Code:** T
EPA Rpt Qty: **DOT Rpt Qty:**
Ozone Depleting Chemical: N

CAS: 1310-58-3 **RTECS #:** TT2100000
Name: POTASSIUM HYDROXIDE
% Text: 6.5 **Code:** M
Environmental Wt: **Other REC Limits:** None Recommended
OSHA PEL: 0.2 MG/M3 **Code:** F **OSHA STEL:** N/P **Code:**
ACGIH TLV: Not Established **Code:** T **ACGIH STEL:** C2 MG/M3 **Code:** T
EPA Rpt Qty: 1000LBS **DOT Rpt Qty:** 1000LBS
Ozone Depleting Chemical: N

Section 3 - Hazards Identification, Including Emergency Overview
TEIG NICKEL METAL HYDRIDE BATTERY

Effects of Single (Acute) Overexposure:

Inhalation:

During normal use inhalation is an unlikely route of exposure due to containment of hazardous materials within the battery case. However, should the batteries be exposed to extreme heat or pressures causing a breach in the battery cell case.

Ingestion:

If the battery case is broken in the digestive tract, the electrolyte may cause localized burns.

Skin Absorption: No evidence of adverse effects from available data.

Skin Contact:

Exposure to the electrolyte contained inside the battery may result in chemical burns. Exposure to nickel may cause dermatitis in some sensitive individuals.

Eye Contact:

Exposure to the electrolyte contained inside the battery may result in severe irritation and chemical burns.

Section 4 - First Aid Measures
TEIG NICKEL METAL HYDRIDE BATTERY

First Aid:

Swallowing: Do not induce vomiting. Seek medical attention immediately.

Skin:

If the internal cell materials of an opened battery cell come into contact with the skin, immediately flush with water.

Inhalation:

If potential for exposure to fumes or dusts occurs, remove immediately to fresh air and seek medical attention.

Eye:

If the contents from an opened battery come into contact with the eyes, immediately flush eyes with water continuously for at least 15 minutes. Seek medical attention.

Neutralizing Agent: Acetic Acid

Section 5 - Fire Fighting Measures
TEIG NICKEL METAL HYDRIDE BATTERY

Fire Fighting Procedures:

If Incinerated, wear NIOSH/MSHA approved SCBA and full protective equipment (FP N).

Unusual Fire or Explosion Hazard:

Exposure to temperature of above 212°F can cause evaporation of the liquid content of the potassium hydroxide electrolyte resulting in the rupture of the cell. Internal short circuit could also cause venting of the electrolyte. There is potential for exposure to iron, nickel, cobalt or rare earth metal fumes during fires.

Extinguishing Media:

Any class of extinguishing medium may be used on the batteries or their packing material.

Section 6 - Accidental Release Measures
TEIG NICKEL METAL HYDRIDE BATTERY

Spill Release Procedures:

Spill and leaks are unlikely because cells are contained in an hermetically-sealed case. If the battery case is breached, don protective clothing that is impervious to caustic materials and absorb or pack spill residues in inert material. Dispose of as a hazardous waste in accordance with applicable state and federal regulations.

Section 7 - Handling and Storage
TEIG NICKEL METAL HYDRIDE BATTERY

Storage:

Store in a cool, dry place. But prevent condensation on cell or battery terminals. Elevated temperatures may result in reduced battery life. Optimum storage temperatures are between -31°F and 95°F. The battery may be highly charged and are capable of high energy discharge. Care should be taken to handle batteries properly to avoid shorting or misuse. That will result in rapid uncontrolled electrical, chemical or heat energy release.

Mechanical Containment:

If there are special encapsulation or sealing requirements, consult your TEIG NICKEL METAL HYDRIDE BATTERY representative about possible cell hazard precautions or limitations.

Handling:

Accidental short circuit will bring high temperature elevation to the battery as well as shorten the battery life. Be sure to avoid prolonged short circuit since the heat can burn attendant skin and even rupture the battery cell case. Batteries packaged in bulk containers should not be shaken. Metal covered tables or belts used for assembly of batteries into devices can be the source of short circuits; apply insulating material to assembly work surface.

Soldering/welding:

If soldering or welding to the case of the battery is required, consult your TEIG NICKEL METAL HYDRIDE BATTERY representative for proper precautions to prevent seal damage or external short circuit.

Charging:

This battery is designed for recharging. A loss of voltage and capacity of batteries due to self-discharge during prolonged storage is unavoidable. Charge battery before use. Observe the specified charge rate since higher rates can cause a rise in internal gas pressure which may result in damaging heat generation or cell rupture and or venting.

Section 8 - Exposure Controls & Personal Protection
TEIG NICKEL METAL HYDRIDE BATTERY

Respiratory Protection: Not required under normal use.

Ventilation: Not required under normal use.

Protective Gloves: Not required under normal use.

Eye Protection: Not required under normal use.

Section 9 - Physical & Chemical Properties
TEIG NICKEL METAL HYDRIDE BATTERY

The information and recommendations set forth are made in good faith and believed to be accurate as of the date of preparation. XUZHOU ENERGY ELECTRONICS CO., LTD makes no warranty, expressed or implied, with respect to this information and disclaims all liabilities reliance on it.

Appearance: Physical shape and color as supplied.

Temperature Range:

Continuous: +5~+25°C
Occasional: -40~+50°C

Specific Energy: 65~75Wh/Kg

Notes: Wh=Nominal Voltage rated Ah as defined in IEC standard.
Kg: Average battery weight in Kg.

Specific Instant Power: About 1500W/Kg

Notes: W=0.5 x Nominal Voltage x Ip
Ip=current in Amperes delivered by a fully charged battery for half the nominal Voltage at one sencond
Kg: Average battery weight in Kg.

Mechanical Resistance: As defined in relevant IEC standard.

Section 10 - Stability & Reactivity Data
TEIG NICKEL METAL HYDRIDE BATTERY

Stability Indicator: YES

Materials to Avoid:

The battery cells are encased in non-reactive container; if container is breached, avoid contact of internal battery components with acids, aldehydes, and carbamate compounds.

Stability Condition to Avoid: Heat, open flames, sparks and moisture.

Hazardous Decomposition Products:

Oxides of NICKEL, COBALT, MANGANESE, LANTHANUM, and CERIUM, POTASSIUM hydroxide.

Hazardous Polymerization Indicator: None

Conditions to Avoid Polymerization: Not Relevant.

Section 11 - Toxicological Information
TEIG NICKEL METAL HYDRIDE BATTERY

Toxicological Information:

Nickel Hydroxide:	LD50/oral/rat: 1600mg/Kg
Potassium Hydroxide:	LD50/oral/rat: 365mg/Kg
Cobalt Hydroxide:	LD50 not available.

Section 12 - Ecological Information

The information and recommendations set forth are made in good faith and believed to be accurate as of the date of preparation. XUZHOU ENERGY ELECTRONICS CO., LTD makes no warranty, expressed or implied, with respect to this information and disclaims all liabilities reliance on it.

Ecological Information:

TEIG NICKEL METAL HYDRIDE BATTERY contains no cadmium, no mercury , no lead and no toxic metals.

Section 13 - Disposal Considerations
TEIG NICKEL METAL HYDRIDE BATTERY

Waste Disposal Methods:

Send to a certified hazardous waste disposal site. Dispose of waste in accordance with local, state and federal laws and regulations. Recycling is recommended. Do not incinerate batteries.

Section 14 - Transportation Information
TEIG NICKEL METAL HYDRIDE BATTERY

TEIG NICKEL METAL HYDRIDE BATTERY do not require specific transport obligations.

Section 15 – Recycling and Disposal
TEIG NICKEL METAL HYDRIDE BATTERY

TEIG encourages battery recycling. Our Nickel Metal Hydride batteries are not defined by the federal government as hazardous waste and are safe for disposal in the normal municipal waste stream.

DO NOT INCINERATE or subject battery cells to temperatures in excess of 212°F. Such treatment can vaporize the liquid electrolyte causing cell rupture.

The information and recommendations set forth are made in good faith and believed to be accurate as of the date of preparation. XUZHOU ENERGY ELECTRONICS CO., LTD makes no warranty, expressed or implied, with respect to this information and disclaims all liabilities reliance on it.

MATERIAL SAFETY DATA SHEET

PRODUCT NAME : NICKEL-METAL HYDRIDE (NiMH) BATTERIES

1. Product Identification

Product Description : Nickel Metal Hydride rechargeable batteries, supplied as individual cells or assembled together as battery packs.

Models / Sizes : All

2. Ingredients

	Approx. percentage of total weight
Nickel (as Nickel, Nickel Hydroxide & Nickel Oxide)	44.0%
Rare Metal (Hydrogen absorbed alloy)	14.5%
Cobalt Hydroxide (as Cobalt Metal)	6.7%
Manganese	2.4%
Aluminium	1.5%
Hydroxyl, Liquid	1.45%
Potassium Hydroxide	1.3%

Boiling point :	Not applicable	Melting Point :	Not applicable
Vapour Pressure:	Not applicable	Vapour Density :	Not applicable
Specific Gravity :	1.17 – 1.25 (electrolyte)	Evaporation Rate :	Not determined
Solubility in water :	Electrolyte solution is completely soluble Remainder – insoluble		

3. Health Hazard Information

All Nickel Metal Hydride cells are manufactured as sealed units. They do not pose a health hazard if kept in a sealed condition and used within their specified operational limits.

The following information is provided to cater for exceptional circumstances only or where the cells have been abused.

The acutely toxic ingredients are Potassium Hydroxide and Nickel compounds.

Overexposure to Cell Contents

Eye Effects : In the case of a fire or cell rupture the electrolyte solution inside the battery is extremely corrosive to eye tissue and may result in permanent blindness. Contact with nickel oxide may cause minor irritation.

Skin Effect : Contact with electrolyte solution inside the battery may cause serious burns to skin tissues. Contact with nickel compounds may result in chronic eczema or nickel itch.

Ingestion : Ingestion of electrolyte causes tissue damage to throat area and gastro/respiratory tract. Ingestion of nickel compounds causes nausea and intestinal disorders.

Inhalation : No exposure possible except in the case of fire or abuse. Effects of inhalation of nickel compounds vary from mild irritation of nasal mucous membranes to damage of lung tissues.

Battery Electrolyte

Eye Contact : Flush with plenty of water for at least 15 minutes if abuse causes safety vents to activate. Obtain immediate medical attention.

Skin Contact : Remove contaminated clothing and flush effected areas with plenty of water for at least 15 minutes. Wash with soap and water.

Ingestion : Do not induce vomiting. Dilute by giving water. Obtain immediate medical attention. Do not give anything by mouth to an unconscious person.

Inhalation : Remove to fresh air. Give oxygen or artificial respiration if needed. Obtain immediate medical attention.

Protection

Eyes : Use splash goggles or face shield if cell vent activates due to abuse.

Skin : If exposure to electrolyte solution, or dried salts is likely, use any water-insoluble non-absorbent glove, i.e., synthetic rubber. Do not use leather or wool.

Respiratory : Use approved respirator if cell broken open during a fire, to maintain exposure levels below the limits for hydrogen absorbed alloy and nickel compounds.

Other Protective Equipment : Rubber apron or equivalent if exposure to electrolyte is likely.

4. Safety Hazard Information

All Nickel Metal Hydride cells are manufactured as sealed units. They do not pose a safety hazard if kept in a sealed condition and used within their specified operational limits.

The following information is provided to cater for exceptional circumstances only or where the cells have been abused.

Fire and Explosion

Extingushing Media :

	Melting Point	Boiling Point
Nickel	2645F / 1452C	4850F / 2677C
Nickel Hydroxide	N/A	445F / 229C (Decomposes to NiO)
Nickel Oxide	3605F / 1985C	90F / 32C (Decomposes to Ni and O2)

Special Fire Fighting Procedure :

Use self-contained breathing apparatus to avoid breathing toxic fumes. Wear protective clothing and equipment to prevent potential body contact with electrolyte solution or mixture of water and solution.

Fire and Explosion Hazards :

Electrolyte solution is corrosive to all human tissues . It will react with many organic chemicals, especially nitro-carbons and chlorocarbons. Electrolyte solution reacts with zinc, aluminium and other active materials, releasing hydrogen gas. In case of fire, do not take in smoke and fume.

Spillage

Electrolyte Spill : Flush with water and neutralize with dilute vitriol.

5. Precautions and comments

Nickel Metal Hydride cells and batteries may be highly charged and capable of high energy discharge. Care should be taken to handle these products properly to avoid shorting or misuse that will result in rapid uncontrolled electrical, chemical or high energy release.

Always use the products within their specified operational limits. Use outside these limits may result in leaking, venting, fire or explosion.

Do not solder directly to the cells or batteries or otherwise overheat.

Do not fit cells or batteries in a sealed enclosure.

Do not mix with batteries of other chemistries, e.g. nickel cadmium.

Do not short circuit - may cause burns or fire.

Do not incinerate - may burst or release toxic materials.

Transportation

Nickel Metal Hydride cells and batteries are considered to be 'dry cell' products which are unregulated for the purpose of transportation. The only requirement for these products is when shipping by air where IATA Special Provision A123 states ' An electrical battery or battery powered device having the potential of dangerous evolutions of heat that is not prepared so as to prevent a short circuit (e.g. in the case of batteries, by the effective insulation of exposed terminals; or in the case of equipment, by disconnection of the battery and protection of exposed terminals) is forbidden from transportation. Sensibly, the same requirements should be applied when shipping these products by land or sea.

Disposal

At the time of issue of this data sheet there were no regulations in force within the UK covering disposal of Nickel Metal Hydride cells and batteries. For environmentally friendly recycling / disposal contact a specialist waste disposal company.

COSHH (Control of Substances Hazardous to Health) Regulations, 1998

Nickel Metal Hydride cells and batteries are not substances hazardous to health within the meaning of these regulations.

This Health and Safety Data Sheet was issued on 2nd June 2005 and supersedes all earlier issues.

Martel Instruments Ltd, Stanelaw Way,
Tanfield Lea Ind Est,
Stanley,
Durham DH9 9XG
UK

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Email : info@martelinstruments.com

www.martelinstruments.com

NiMH/MSDS/A

MATERIAL SAFETY DATA SHEET FOR THE i-STAT 65µL CAPILLARY DISPENSERS

Note: In the following MSDS sheet from Drummond Scientific Company, the MSDS information is listed separately for the 3 main components of the capillary dispensers: one section for the heparin salts, one section for the neutral borosilicate glass, and one for the Mylar® Polyester Film.

CELSUS®

MATERIAL SAFETY DATA SHEET

HEPARIN SALTS

SECTION 1

Manufacturer's Name: Celsus Laboratories, Inc. **Emergency Telephone:** (800)-heparin; **Address:** 12150 Best Place, Cincinnati, Ohio 45241-1569 U.S.A.; E-mail info@heparin.com; **Chemical Name:** Heparin Salts (Ammonium, Calcium, Lithium, Sodium, Zinc, Ardeparin Sodium); **Chemical Family:** Glycosaminoglycans/ Sulfomucopoly-saccharides/Polyanions; **Therapeutic Category:** Anticoagulant of blood; **CASRN:** 9041-08-1 (Na); 60800-63-7 (NH4); 9045-22-1 (Li); 37270-89-8 (Ca).

SECTION II - HAZARDOUS INGREDIENTS

OSHA Hazard Communication Rule, 29 CFR 1910.1200: None found

SECTION III - PHYSICAL DATA

Appearance and Odor..	White powder, practically odorless
Solubility In Water..	25 g/100mL minimum
Percent Volatile by Volume (%)............................	None

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surroungin fire and materials. As with all fires, evacuate personnel to safe areas. Self-contained breathing equipment and protective clothing recommended for firefighters.

SECTION V - HEALTH HAZARD DATA

Treshold Limit Value: None established

Effects Of Overexposure:

TDLo...7 mg/kg/4D subcutaneous-man;	LD$_{50}$... 354 mg/kg oral-rat
TDLo...1400 units/kg/1W-I subcutaneous-woman;	LD$_{50}$... 2800 mg/kg intravenous-mouse
TDLo...700 units/kg/13D-I intravenous-woman;	LD$_{50}$... 1000 mg/kg intravenous-dog;

Emergency and First Aid procedures: Can cause irritation. Upon eye or skin contact, remove to fresh air and flush with copious amounts of water. Obtain medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen. **Precautions to consider:** Those developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Avoid contact with eyes, skin or clothing. Avoid breathing dust. **Carcinogen or potential carcinogen:** Not listed (National Toxicology Program/IARC and OSHA)

SECTION VI - REACTIVITY DATA

Stability: Stable; **Hazardous Depolymerization:** Will not occur; **Hazardous Decomposition Products:** None; **Incompatibility:** None

SECTION VII - SPILL OR LEAK PROCEDURES

Steps to be taken in case material is released or spilled: Sweep up material for recovery - Handle with care to ensure product integrity. **Waste Disposal Method:** Sweep up for recovery

SECTION VIII - SPECIAL PROTECTION INFORMATION

Respiratory Protection: NIOSH approved dust respirator, local ventilation recommended. **Protective Gloves:** Required to avoid prduct contamination. **Other Protective Equipment:** Safety goggles and lab apparel.

SECTION IX - SPECIAL PRECAUTIONS

Handling and Storage: Store in tightly sealed (55 inchpounds) original containers - Protect from heat, low pH and moisture. **Other Precautions:** Follow GMP when handling material.

The above information has been developed by Celsus from sources considered reliable but has not been
independently verified by Celsus. Therefore, Celsus cannot guarantee the accuracy of the information. No
representation or warranty, express or implied, including warranties of merchantability and fitness for a particular
purpose is made with respect to the information contained herein.

FDA Drug Establishment # 1527761

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MATERIAL SAFETY DATA SHEET

Identity: N51A Glass

Chemical and Common Names: Neutral Borosilicate Glass

Section I

Manufacturer's Name: Kimble Glass, Inc.
Address: 537 Crystal Ave.
Vineland, NJ 08360-3257
Signature of Preparer: R. P. Abendroth

Emergency Number: (609) 692-3600
Date Prepared: June 10, 1992

Section II (Hazardous Ingredients/Identity Information)

Hazardous Components	CAS#	PEL(mg/m³)	TLV(mg/m³)	% (optional)
Silicon Dioxide	14808-60-7	N/A	N/A	72
Boron oxide	1303-86-2	15	10	12
Aluminum oxide	1344-28-1	N/A	10	7
Potassium oxide	12136-45-7	N/A	N/A	2
Sodium oxide	12401-86-4	N/A	N/A	6
Calcium oxide	1305-78-8	5	2	1

Section III (Physical/Chemical Characteristics)

Boiling Point: N/A
Vapor Pressure (mmHg): N/A
Vapor Density: N/A
Solubility in Water: N/A
Appearance and Odor: clear glass, no odor

Specific Gravity: 2.33
Melting Point: N/A
Evaporation Rate: N/A

Section IV (Fire and Explosion Hazard Data)

Flash Point: N/A Flammable Limits: LEL: N/A UEL: N/A
Extinguishing Media: Not Combustible. Use same as for surrounding area.
Special Fire Fighting Procedures: Wear pressure demand self contained breathing apparatus in conjunction with appropriate personal protective equipment.
Unusual Fire and Explosion Hazards: None

Free silica particles on contact with the eye may cause a reaction that could damage vision. Symptoms would include a gradual clouding of vision. See First Aid below on how to avoid.

CARCINOGENICITY(of product): NTP: No IARC Monographs: No
OSHA Regulated: No

SIGNS AND SYMPTOMS OF EXPOSURE: Silicosis generally develops after years of repeated high exposure.

MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: None, unless heavy dust exposure is involved, in which case lung disease may be aggravated.

EMERGENCY FIRST AID PROCEDURES: If dust or particles contact eye, flush with water, but do not attempt to remove particles. Seek immediate medical attention.

Section VII (Precautions for Safe Handling and Use)

Steps to be taken in Case Material is Released or Spilled: Sweep, shovel, or vacuum spilled material into a closed container. Avoid generation of dust.

Waste Disposal Method: Dispose of in accordance with local, state, and/or Federal Regulations

Precautions to be taken in Handling and Storing: Store in dry, cool location.

Other Precautions: none

MSDS
MATERIAL SAFETY DATA SHEET

DuPont Polymers

MYL014 Revised 19-OCT-1996 Printed 20-JUN-1997

"MYLAR" POLYESTER FILMS IN SYNONYM LIST MYL014

CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification
"MYLAR" is a registered trademark of DuPont.

Corporate MSDS Number DU007097

Tradenames and Synonyms
"MYLAR" OLAF, OLAFT

Tradenames and Synonyms (Remarks)
Polyethylene terephthalate with anti-fogging agent.

Company Identification
MANUFACTURER/DISTRIBUTOR
DuPont Packaging & Industrial Polymers
1007 Market Street
Wilmington,DE 19898

PHONE NUMBERS

Product Information	1-(800)-441-7515
Transport Emergency	1-(800)-424-9300
Medical Emergency	1-(800)-441-3637

COMPOSITION/INFORMATION ON INGREDIENTS

Components

Material	**CAS Number**	%
POLYETHYLENE TEREPHTHALATE	25038-59-9	>84.5
Non-Regulated polymer coating		<15
Talc	14807-96-6	<1

Components (Remarks)
Material is not known to contain Toxic Chemicals under Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR part 372.

No components are hazardous as defined by 29CFR1910.1200

(Continued)

HAZARDS IDENTIFICATION

Potential Health Effects

Before using "Mylar" Polyester Film, read the bulletin on safe handling instructions (E-60736).

ACUTE OR IMMEDIATE EFFECTS: ROUTES OF ENTRY AND SYMPTOMS

INGESTION "Mylar" was fed to male and female rats and dogs for ninety days at the 10% level in their diet. No compound related effects were seen. "Mylar" has low ingestion toxicity.

SKIN No animal tests have been run. However, based on many years of manufacturing these products, no skin problems are anticipated from normal handling of the film.

EYE Mechanical irritaion.

INHALATION Not volatile as marketed. Fumes irritating to the eyes, nose, and throat may be produced at temperatures above about 235 degrees C. The exposure may result in reddening, tearing, and itching of the eyes, soreness in the nose and throat, and caughing.

Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

FIRST AID MEASURES

First Aid

INHALATION
No specific intervention is indicated as the compound is not likely to be hazardous by inhalation. Consult a physician if necessary. If exposed to fumes from overheating or combustion, move to fresh air. Consult a physician if symptoms persist.

SKIN CONTACT
The compound is not likely to be hazardous by skin contact, but cleansing the skin after use is advisable. If molten polymer gets on skin, cool rapidly with cold water. Do not attempt to peel polymer from skin. Obtain medical treatment for thermal burn.

EYE CONTACT
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INGESTION
No specific intervention is indicated as compound is not likely to be hazardous by ingestion. Consult physician if necessary.

(Continued)

FIRE FIGHTING MEASURES

Flammable Properties
The solid film can be combusted only with difficulty.

Fire and Explosion Hazards:

Hazardous gases/vapors produced in a fire are carbon dioxide, carbon monoxide, organic acids, aldehydes, and alcohols.

Extinguishing Media
Water, Foam, Dry Chemical, CO2.

Fire Fighting Instructions
Keep personnel removed and upwind of fire. Wear self-contained breathing apparatus. Wear full protective equipment.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)
NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

HANDLING AND STORAGE

Handling (Personnel)
Avoid breathing vapors and fumes produced during processing.

Storage
Store in a cool, dry place. Keep packages closed to prevent contamination.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls
VENTILATION Normal ventilation except at temperatures above 235 degrees C where local exhaust ventilation may be required.

Personal Protective Equipment

Eye/Face	Safety Glasses.
Respirator	Not required.
Protective Gloves	Wear gloves when handling hot film.

# **Exposure Guidelines**
Exposure Limits
"MYLAR" POLYESTER FILMS IN SYNONYM LIST MYL014

PEL (OSHA)	Particulates (Not Otherwise Regulated) 15 mg/m3, 8 Hr. TWA, total dust 5 mg/m3, 8 Hr. TWA, respirable dust

(Continued)

EXPOSURE CONTROLS/PERSONAL PROTECTION(Continued)

Other Applicable Exposure Limits

POLYETHYLENE TEREPHTHALATE

PEL	(OSHA)	None Established
TLV	(ACGIH)	None Established
AEL *	(DuPont)	10 mg/m3, 8 Hr. TWA, total dust 5 mg/m3, 8 Hr. TWA, respirable dust

Talc

PEL	(OSHA)	Respirable dust, 1/2*(80 mg/m3 / % SiO2) as 8 Hr TWA
TLV	(ACGIH)	2 mg/m3, respirable dust, 8 Hr. TWA, A4
AEL *	(DuPont)	0.5 mg/m3, 8 & 12 Hr. TWA respirable dust

* AEL is DuPont's Acceptable Exposure Limit. Where governmentally imposed occupational exposure limits which are lower than the AEL are in effect, such limits shall take precedence.

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Melting Point	~235 C (~455 F)
% Volatiles	Negligible
Solubility in Water	Negligible
Odor	Negligible
Form	Transparent film
Color	Clear

Physical Hazards

During processing, the film can pick up a strong static charge. Avoid discharge into dust or solvent-laden air, as flash fire or explosion may result.

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

Decomposition

Hazardous gases/vapors produced are carbon monoxide and hydrocarbon oxidation products including organic acids, aldehydes, and alcohols.

Polymerization

Polymerization will not occur.

Other Hazards

Conditions to Avoid: Temperatures >235 deg C (455 deg F). Strong acids and bases may hydrolyze the film.

(Continued)

DISPOSAL CONSIDERATIONS

Waste Disposal

Preferred options for disposal are (1) recycling, (2) incineration with energy recovery, and (3) landfill. The high fuel value of this product makes option 2 very desirable for material that cannot be recycled. Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state/provincial, and local regulations.

TRANSPORTATION INFORMATION

Shipping Information

DOT

Proper Shipping Name	Not regulated

REGULATORY INFORMATION

U.S. Federal Regulations

TSCA Inventory Status	Listed.

State Regulations (U.S.)

STATE RIGHT-TO-KNOW LAWS

No substances on the state hazardous substances list, for the states indicated below, are used in the manufacture of products on this Material Safety Data Sheet.

SUBSTANCES ON THE PENNSYLVANIA HAZARDOUS SUBSTANCES LIST PRESENT AT A CONCENTRATION OF 1% OR MORE (0.01% FOR SPECIAL HAZARDOUS SUBSTANCES): None known.

WARNING: SUBSTANCES KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER, BIRTH DEFECTS OR OTHER REPRODUCTIVE HARM: None known.

SUBSTANCES ON THE NEW JERSEY WORKPLACE HAZARDOUS SUBSTANCE LIST PRESENT AT A CONCENTRATION OF 1 % OR MORE (0.1% FOR SUBSTANCES IDENTIFIED AS CARCINOGENS, MUTAGENS OR TERATOGENS): None known.

OTHER INFORMATION

Additional Information

MEDICAL USE: CAUTION: Do not use in medical applications involving permanent implantation in the human body. For other medical applications see DuPont CAUTION Bulletin No. H-50102.

(Continued)

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

Responsibility for MSDS	T. E. SCHROER
Address	DUPONT PACKAGING & INDUSTRIAL POLYMERS CHESTNUT RUN PLAZA 713 WILMINGTON, DE 19880-0713
Telephone	302-999-4664

# Indicates updated section.

End of MSDS

MORE DIAGNOSTICS, INC.

MATERIAL SAFETY INFORMATION

Attention: Safety Director

Product: **i-STAT Cardiac Markers Controls and Calibration Verification Set**

i-STAT Cardiac Markers Controls are not considered to be or to contain hazardous chemicals based on evaluations made by our company under the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

The product is made entirely of human-based serum and analytes, with a trace amount of preservative added, and is packaged in 1 mL vials. A spill of that volume would have insignificant chemical content, and can be cleaned up with a disposable wipe.

Although there is no chemical hazard associated with this product, any material of human origin should be treated as a biohazard. Biohazard warnings are included in the package insert Instructions For Use.

Wayne L. Hamari
QA/RA Officer
More Diagnostics, Inc.

APPROVED: __
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Rev. No. One 10/06

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www.CLINIQA.com

CLINIQA

MATERIAL SAFETY DATA SHEET

Center for Disease Control
Emergency Telephone Number: (404) 633-5313

IDENTIFICATION:

i-STAT Part Number:	016646-01
Abbott Reference Number:	06F12-09
Product Name:	Cardiac Marker Control, Level 1, i-Stat
i-STAT Part Number:	016647-01
Abbott Reference Number:	06F12-10
Product Name:	Cardiac Marker Control, Level 2, i-Stat
i-STAT Part Number:	016648-01
Abbott Reference Number:	06F12-11
Product Name:	Cardiac Marker Control, Level 3, i-Stat
i-STAT Part Number:	016649-01
Abbott Reference Number:	06F12-12
Product Name:	Cardiac Marker Control, Tri-level, i-Stat

TOXICITY HAZARDS:

Possible biohazard

HEALTH HAZARD DATA:

Acute Effects:

Potential infectious agent. May be harmful by inhalation, ingestion, or skin absorption. May cause irritation.
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

First Aid:

In case of contact, immediately wash skin with soap and copious amounts of water.
Consult a physician.

Safety Notice:

Because no test method can offer complete assurance that products derived from human source will not transmit infectious agents, it is recommended that this product be handled with the same precautions used for patient specimens.

PHYSICAL DATA:

Data not available

FIRE AND EXPLOSION HAZARD DATA:

Poses no unusual fire or explosion hazards. Extinguish by any means appropriate to the surrounding fire.

REACTIVITY DATA:

No unusual reactivity hazards or incompatibilities.

SPILL/LEAK AND WASTE DISPOSAL PROCEDURES:

Spills:

Wear protective equipment. Collect or absorb onto an inert material. Place in suitable container for prompt disposal. Label the container as to the potential infectious hazard. Spill areas can be decontaminated with 0.5% sodium hypochlorite, e.g., a 1:10 dilution of common household bleach, i.e., Clorox, that is prepared fresh each month.

Waste Disposal Method:

No special precautions. Dispose of by means as to comply with all local, state and federal regulations.

HANDLING AND STORAGE PRECAUTIONS:

Wear gloves.
Avoid breathing dust or aerosols.
Avoid contact with eyes, skin, and clothing.
Wash thoroughly after handling.
Keep container closed.
Store at the recommended label temperature.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Cliniqa Corporation shall not be held liable for any damage resulting from handling or from contact with the above product.

MORE DIAGNOSTICS, INC.

MATERIAL SAFETY INFORMATION

Attention: Safety Director

Product: **i-STAT BNP Controls and Calibration Verification Set**

i-STAT BNP Controls are not considered to be or to contain hazardous chemicals based on evaluations made by our company under the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

The product is made of human-based EDTA plasma and analytes with trace amounts of preservative and stabilizers added, and is packaged in 1 mL vials. A spill of that volume would have insignificant chemical content, and can be cleaned up with a disposable wipe.

Although there is no chemical hazard associated with this product, any material of human origin should be treated as a biohazard. Biohazard warnings are included in the package insert Instructions For Use.

Wayne L. Hamari
QA/RA Officer
More Diagnostics, Inc.

APPROVED: __
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Rev. No. One 10/06

P.O. Box 6714, Los Osos, CA 93412 USA · (805)528-6005 · Fax (805)528-3532
E-mail: info@morediagnostics.com

Procedure Manual

for the i-STAT® System

This Procedure Manual is intended to be a template for the Procedure Manual required by CLIA and laboratory accreditation bodies. This Procedure Manual should be customized for site-specific policies and procedures. The Procedure Manual is provided on CD-ROM for this purpose. This Procedure Manual is not intended to replace the System Manual.

i-STAT is a registered trademark of Abbott Laboratories

Abbott
Point of Care

ART: 714446-00D REV. DATE 07/23/06

PROCEDURE MANUAL FOR THE i-STAT SYSTEM

Contents

System Overview 1
  Analyzers
  Analysis Time
  Cartridges
  Glucose Test Strips
  Central Data Station or Data Manager

Supplies and Storage Requirements 1-2
  Cartridges
  Glucose Test Strips
  Controls

Blood Specimens 2-5
  Blood Collection Equipment
  Blood Volume
  Suitable Specimens
  Specimen Labeling
  Specimen Collection and Handling
  Criteria for Specimen Rejection
  Precautions

Procedure for Analysis 6-10
  Preparation for Use
  Procedure for Cartridge Testing
  Procedure for Glucose Test Strip Testing
  Alternative Procedure

Results 11-18
  Calculations
  Displayed Results
  Suppressed Results
  Printing and Transmitting Results
  Reference Ranges and Reportable Ranges
  Critical Results
  Interferences

Quality Control 19-25
  Daily Procedures
  Monthly Procedures
  Periodic Procedures

Calibration 25

Clinical Significance 26-28

Principles of Measurement 29-30

References 31

Logs .... **i-vii**

PROCEDURE MANUAL FOR THE i-STAT SYSTEM

SYSTEM OVERVIEW

The i-STAT System incorporates comprehensive components needed to perform blood analysis at the point of care. The System consists of the following primary components:

Analyzers

Analyzers can be the i-STAT Portable Clinical Analyzer, the i-STAT 1 Analyzer, or the Blood Analysis Module, which is used in conjunction with the Philips Medical Systems (formerly Agilent Technologies) CMS and 24/26 Patient Monitor. When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring. A MediSense® Precision PCx™ or PCx™ Plus Glucose Test Strip is scanned and inserted into the i-STAT 1 Analyzer and a drop of whole blood is applied to the target area of the test strip.

Analysis Time

- ☐ ACT cartridge: to detection of end point - up to 1000 seconds (16.7 min.)
- ☐ PT/INR cartridge: to detection of end point – up to 300 seconds (5 min.)
- ☐ cTnI and BNP cartridges: 600 seconds (10 min.)
- ☐ CK-MB Cartridge: 300 seconds (5 min.)
- ☐ Other cartridges: typically 130 to 200 seconds
- ☐ MediSense Precision PCx or PCx Plus Glucose Test Strip: 20 seconds

Cartridges

A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. Sensors for analysis of pH, PCO_2, PO_2, TCO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, creatinine,
urea nitrogen (BUN) and hematocrit are available in a variety of panel configurations. Cartridges are also available for Celite-ACT, Kaolin-ACT, PT/INR, Troponin I/cTnI, CK-MB and BNP (Table 1). A whole blood sample of approximately 1 to 3 drops is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

Glucose Test Strips

The i-STAT 1 Analyzer is capable of using the Abbott MediSense Precision PCx or PCx Plus Blood Glucose Test Strips.

Central Data Station or Data Manager

A dedicated desktop computer with the i-STAT Central Data application provides the primary information management capabilities for the i-STAT System. IR Links for Portable Clinical Analyzers, Downloaders and Downloader/Rechargers for the i-STAT 1 Analyzers and a Philips installed server for Blood Analysis Modules allow for transmission of patient records from a widely distributed network of analyzers to the Central Data Station application. Data can be stored, organized, edited, and transferred to a laboratory information system or other computer system. Cartridge usage and efficiency reports can be generated for management of the System.

SUPPLIES and STORAGE REQUIREMENTS

Cartridges

Cartridges are sealed in individual pouches or portion packs. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). **Do not allow cartridges to freeze.** Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to temperatures above 30°C (86°F). If the pouch has been punctured, the cartridge should not be used. Write the date on the cartridge box or individual cartridge pouches to indicate the two-week room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

Glucose Test Strips

Test strips are sealed in individual foil packets. Store the strips at a temperature between 4 and 30°C (39 and 86°F). When stored properly, the unopened test strips remain stable until the expiration date printed on the barcode label. Do not freeze and keep out of direct sunlight.

Controls

i-STAT Controls for blood gases, electrolytes, and chemistries

Store at 2 to 8°C (35° to 46°F). Controls may be stored at room temperature (18 to 30°C or 64 to 86°F) for five days. Do not use after expiration date on the box and ampules.

i-STAT Controls for ACT and PT/INR

Store at 2 to 8°C (35° to 46°F). Do not use after expiration date on the box and vials. Controls should be used immediately after reconstitution.

i-STAT Controls for cTnI and BNP

Store at ≤ -18°C (-1°F) in a non-defrosting freezer. After thawing, the opened or unopened 1.0 mL vial is stable for 4 hours when capped and stored at 2 to 8°C (35° to 46°F). Do not refreeze

CLINIQA Liquid Cardiac Marker Control for CK-MB

This control requires no reconstitution or frozen storage. It is stable until the expiration date on the vial label when stored unopened at 2 to 8°C. Once opened, CLINIQA Liquid Cardiac Marker Control is stable for 30 days when stored tightly capped at 2 to 8°C.

Hematronix Meter Trax ™ Whole Blood Reference Controls for Hematocrit

Store upright at 2 to 8°C (35° to 46°F). Do not allow to freeze. Ensure control is completely mixed before using. Once opened, bottles may be used for up to 31 days provided they have been resealed and refrigerated immediately after each use. Write the date of opening on the bottle label. Do not use after expiration date on box and vials.

RNA Medical Hematocrit Control

RNA Medical Hematocrit Control is stable until the expiration date stated on the ampule when stored at temperatures of 2 to 25°C. Do not freeze or expose ampules to temperatures greater than 30°C. If stored refrigerated, the control material should be equilibrated to room temperature for at least 4 hours prior to testing.

Electronic Simulator

Store at room temperature and protect contact pads from contamination by replacing the plastic cap and placing the Electronic Simulator in its protective case after use.

MediSense Precision Glucose Control Solutions for test strips

Store the controls at temperatures between 4 and 30°C (39 and 86°F). Do not freeze. Each bottle of control solution is stable for 90 days after opening. Write the date of opening on the bottle label. Always make sure the cap is returned to the correct bottle and tightly closed immediately after use.

BLOOD SPECIMENS

Blood Collection Equipment

Cartridges for Blood Gas/Electrolytes/Chemistries/Hematocrit

- ☐ Skin puncture: lancet and capillary collection tube (plain, lithium heparin, or balanced heparin for electrolytes and blood gases)
- ☐ Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g., 1cc syringe and a 16 to 20 gauge needle).
- ☐ Arterial puncture: Plain syringe or blood gas syringe with heparin and labeled for the assays performed or with the least amount of heparin to prevent clotting (10 U heparin/mL of blood)

Cartridges for ACT

- ☐ Skin puncture: not recommended
- ☐ Venipuncture and arterial puncture: plain plastic syringe without anticoagulant

Glucose Test Strips

- ☐ Skin puncture: lancet and capillary collection tube with lithium heparin, sodium heparin, or EDTA or direct application of sample to test strip
- ☐ Venipuncture and arterial puncture: collection tube or syringe with lithium heparin, sodium heparin, or EDTA

Cartridges for PT/INR

- ☐ Skin puncture: lancet only needed. Cartridge can be filled directly from the finger.
- ☐ Venipuncture and arterial puncture: plain plastic syringe without anticoagulant.

Cartridges for Troponin I/ cTnI and CK-MB

- ☐ Skin puncture: not recommended.
- ☐ Venipuncture: lithium or sodium heparin collection tubes and disposable transfer device (e.g. 1 cc syringe and a 16 to 20 gauge needle). Alternately, a plain syringe or plain collection tube and disposable transfer device can be used if the sample is tested within one minute of patient draw.

Cartridges for BNP

- ☐ Skin puncture: not recommended.
- ☐ Venipuncture: plastic EDTA collection tubes and disposable transfer device (e.g. 1 cc syringe and a 16 – 20 gauge needle) or plastic EDTA syringe.

Blood Volume

See Table 1 below for cartridge volumes. For the glucose test strip, sufficient sample to cover target area - approximately one drop, is required.

Table 1: Cartridge Panel Configurations and Blood Volume (Shading denotes calculated values)

Cartridge	Vol. µL	pH	PCO_2	PO2	Na	K	Cl	iCa	Glu	BUN	Creat	Lact	Hct	TCO_2	ACT	PT/INR	CK-MB	cTnI	BNP	HCO3	TCO2	SO2	BE	Anion Gap	Hb
CHEM8+	95				●	●	●	●	●	●	●		●	●										●	●
CG8+	95	●	●	●	●	●		●	●				●							●	●	●	●		●
EG7+	95	●	●	●	●	●		●					●							●	●	●	●		●
EG6+	95	●	●	●	●	●							●							●	●	●	●		●
CG4+	95	●	●	●								●								●	●	●	●		
G3+	95	●	●	●																●	●	●	●		
EC8+	65	●	●		●	●	●		●	●			●							●	●		●	●	●
6+	65				●	●	●		●	●			●												●
EC4+	65				●	●			●				●												●
E3+	65				●	●							●												●
G	65								●																
Crea	65										●														
ACT	40														●										
PT/INR	20															●									
cTnI	17																	●							
CK-MB	17																●								
BNP	17																		●						

Suitable Specimens for Cartridges for Blood Gases, Electrolytes, Chemistries, and Hematocrit

- ☐ Fresh whole blood collected in a plain capillary collection tube or capillary collection tube with balanced heparin.
- ☐ Fresh whole blood collected in a collection tube with lithium or sodium heparin anticoagulant. Fill collection tubes to capacity.
- ☐ Fresh whole blood collected in a plain plastic syringe or in a blood gas syringe labeled for the assays to be performed. Fill syringes for correct blood-to-heparin ratio.

Suitable Specimens for ACT

- ☐ Fresh whole blood without anticoagulant collected in a plastic syringe. If from an indwelling line, flush the line with 5mL saline and discard the first 5mL of blood or three to six dead space volumes of the catheter.
- ☐ Fresh whole blood collected in a plastic tube without anticoagulant, clot activators, or serum separators. Device used to transfer sample to cartridge must be plastic.

Suitable Specimens for PT/INR

- ☐ Fresh whole blood without anticoagulant collected in a plastic syringe or plastic evacuated tube without clot activators or serum separators. Device used to transfer sample to cartridge must be plastic.
- ☐ Fresh capillary whole blood dispensed directly into the cartridge from the finger.

Suitable Specimens for Glucose Test Strip

- ☐ Fresh capillary whole blood collected in a capillary collection tube containing sodium heparin, lithium heparin, or EDTA. Test immediately.
- ☐ Fresh venous whole blood collected in a collection tube containing sodium heparin, lithium heparin, or EDTA. Test within 30 minutes of collection.
- ☐ Fresh arterial whole blood collected in a syringe containing sodium heparin, lithium heparin, or EDTA. Test within 30 minutes of collection.

Suitable Specimens for Troponin I/cTnI and CK-MB

- ☐ Fresh heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium or sodium heparin. Collection tubes must be filled at least half full.
- ☐ Non heparinized whole blood samples tested within one minute of patient draw collected into a plastic syringe or plastic evacuated tube containing no additives.

Suitable Specimens for BNP

- ☐ EDTA whole blood plasma samples collected in plastic syringes or evacuates tubes containing EDTA. Collection tubes must be filled at least half full.

Specimen Labeling

Unless the specimen is analyzed immediately after collection and then discarded, the specimen container must be labeled with the following information:

Patient name, sex, age
Patient ID number
Time and date of collection
Phlebotomist ID
Doctor’s name

Specimen Collection and Handling

In-Dwelling Line

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle. If collecting sample for ACT, clear the line first with 5mL saline and discard the first 5mL of blood.

Arterial Specimens

For cartridge testing of blood gases, electrolytes, chemistries, and hematocrit, fill a plain syringe or fill a blood gas syringe, labeled for the assays to be performed, to the recommended capacity, or use the least amount of liquid heparin anticoagulant that will prevent clotting. Under-filling syringes containing liquid heparin will decrease results due to dilution and will decrease ionized calcium results due to binding. For ionized calcium, balanced or low volume heparin blood gas syringes should be used. Do not expose sample to air or $\boldsymbol{P}CO_2$ may decrease, pH may increase and $\boldsymbol{P}O_2$ may decrease if the value is above or increase if the value is below the $\boldsymbol{P}O_2$ of room air (approximately 150 mmHg).

For cartridge testing of ACT, use only a plain, plastic syringe without anticoagulant.

For glucose test strips, fill to capacity a syringe or collection tube containing lithium heparin, sodium heparin, or EDTA.

Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds. Discard the first two drops of blood. For blood gas testing, avoid or remove immediately any air drawn into syringe to maintain anaerobic conditions.

Test samples collected without anticoagulant immediately. Test samples for ACT, PT/INR and lactate immediately. For pH, blood gases, TCO_2 and ionized calcium, test within 10 minutes of collection. If not tested immediately, remix the sample and discard the first two drops of blood from a syringe before testing. Note that it may be difficult to property remix a sample in a 1.0 cc syringe. For the glucose test strip and other cartridge tests, test sample within 30 minutes of collection.

Venous Specimens

For cartridge testing of electrolytes, chemistries, and hematocrit, collect sample into an evacuated blood collection tube or a syringe containing sodium, lithium, or balanced heparin anticoagulant. For ionized calcium measurements, balanced heparin or 10 U of sodium or lithium heparin/mL of blood is recommended. Fill tubes to capacity; fill syringes for correct heparin-to-blood ratio. Incomplete filling causes higher heparin-to-blood ratio, which will decrease ionized calcium results and may affect other results. The use of partial – draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for blood gas or CHEM8+ cartridges because of the potential for decreased $\boldsymbol{P}$CO2, HCO_3 and TCO_2 values.

For cartridge testing of ACT or PT/INR, use only a plain, plastic syringe or collection tube containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample from a tube to a cartridge.

For glucose strip testing, EDTA is also an acceptable anticoagulant. ***EDTA is the only acceptable anticoagulant for BNP Cartridge testing.***

Mix blood and anticoagulant by inverting a tube gently at least ten times. Roll a syringe vigorously between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds, then discard the first two drops of blood. Note that it may be difficult to properly mix a sample in a 1 cc syringe.

Test Sample collected without anticoagulant immediately. Test samples for ACT, and lactate PT/INR immediately. Test samples for pH, $\boldsymbol{P}$CO2, TCO_2 and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For the glucose test strip and other cartridge tests, test sample within 30 minutes of collection.

Finger and Heelstick Specimens

For tests other than PT/INR, wipe away the first drop of blood, which contains excess tissue fluid which can increase the potassium result and decrease other test results. Avoid drawing air into the capillary tube. Use balanced heparin or plain capillary tubes for ionized calcium. Test samples immediately to avoid clotting (especially in neonates). **Capillary samples are NOT recommended for ACT, Troponin I/cTnI, CK-MB and BNP.**

Criteria For Specimen Rejection

- ☐ Evidence of clotting
- ☐ Specimens collected in vacuum tubes with anticoagulant other than lithium or sodium heparin (or EDTA for BNP cartridges).
- ☐ Specimens for ACT or PT/INR collected in glass syringes or tubes or with anticoagulant of any kind
- ☐ Syringe for pH, ***P***CO$_2$, ***P***O$_2$ and TCO$_2$ with air bubbles in sample
- ☐ Incompletely filled vacuum tube for the measurement of ionized calcium, ***P***CO$_2$, HCO$_3$ or TCO$_2$
- ☐ Other sample types such as urine, CSF, and pleural fluid

Precautions: Avoid the Following Circumstances

- ☐ Drawing a specimen from an arm with an I.V.
- ☐ Stasis (tourniquet left on longer than one minute before venipuncture)
- ☐ Extra muscle activity (fist pumping)
- ☐ Hemolysis (alcohol left over puncture site, or a traumatic draw)
- ☐ Icing before filling cartridge
- ☐ Time delays before filling cartridge, especially lactate, ACT, and PT/INR
- ☐ Exposing the sample to air when measuring pH, ***P***CO$_2$, ***P***O$_2$ and TCO$_2$.

PROCEDURE FOR ANALYSIS

Preparation for Use

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Glucose test strips require no preparation for use.

Procedure for Cartridge Testing (other than PT/INR, Tropnin I/cTnI, CK-MB or BNP)

1. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well.
3. Dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
4. Close the cover over the sample well until it snaps into place. (Do **not** press over the sample well.)
5. Insert the cartridge into the cartridge port on the analyzer until it clicks into place. When using an ACT cartridge, the analyzer must remain horizontal during the testing cycle.
6. Never attempt to remove a cartridge while the LCK or “Cartridge Locked” message is displayed.
7. Enter an operator ID number. Repeat if required.
8. Enter the patient ID number. Repeat if required.
9. Select tests to be reported, if prompted.
10. Enter additional parameters on the Chart Page if required:
    - ☐ Patient temperature can be entered as degrees Centigrade or Fahrenheit. (Use the * key on the i-STAT Portable Analyzer for a decimal point.)
    - ☐ FIO$_2$ can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
    - ☐ Fields 1, 2, and 3 are user-defined fields, typically used for ventilator settings such as PIP or PEEP.
    - ☐ Choose the number corresponding to the type of sample used when prompted at the Sample Type field. Select CPB for patient in cardiopulmonary bypass surgery.
11. View results shown on the analyzer’s display screen.
12. Remove the cartridge after the LCK or “Cartridge Locked” messages disappears is ready for a new cartridge immediately.

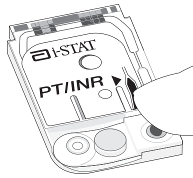
Procedure for the i-STAT 1 Analyzer with Information First

1. Turn the analyzer on and press 2 for i-STAT Cartridge.
2. Scan or enter the operator and patient IDs. Repeat if prompted.
3. Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
4. Following thorough mixing of the sample, direct the dispensing tip or capillary tube containing the blood into the sample well and dispense the sample until it reaches the fill mark on the cartridge and the well is about half full.
5. Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
6. Insert the cartridge into the cartridge port until it clicks into place. When using an ACT cartridge, the analyzer must remain horizontal during the testing cycle.
7. Select tests to be reported, if prompted.
8. Enter additional parameters on the Chart page if required:
   - ☐ Choose the number corresponding to the type of sample used when prompted at the Sample Type field.
   - ☐ Fields 1, 2, and 3 are user-defined fields, typically used for ventilator settings such as PIP or PEEP.
   - ☐ Patient temperature can be entered as degrees Centigrade or Fahrenheit.
   - ☐ FIO_2 can be entered as the number of liters or as a percentage of the oxygen a patient is receiving.
   - ☐ Choose 1-YES or 2-NO for CPB.
   - ☐ Press the → key to return to the results page.
9. View results shown on the analyzer's display screen.
10. Enter Comment Code if prompted.
11. Remove the cartridge after "Cartridge Locked" message disappears. The analyzer is ready for the next test immediately.

Procedure for PT/INR Cartridge Testing

Skin Punctures

1. Remove cartridge from foil pouch and place the cartridge on a flat surface.
2. Prepare lancet device and set aside until needed.
3. Clean and prepare the finger to be sampled. Allow finger to dry thoroughly before sampling.
4. Prick the bottom side of the fingertip with the lancet device.
5. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. Avoid strong repetitive pressure, ("milking") as it may cause hemolysis or tissue fluid contamination of the specimen.
6. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
7. Apply sample until it reaches the fill mark indicated on the cartridge.
8. Fold the sample closure over the sample well.
9. Press the rounded end of the closure until it snaps into place.
10. Insert the cartridge into the cartridge port until it snaps into place.
11. Enter an operator ID number. Repeat if required.
12. Enter the patient ID number. Repeat if required.
13. Select tests to be reported, if prompted.
14. Enter additional parameters on the Chart Page, if required.
15. View result on the analyzer's display screen.
16. Remove the cartridge after "Cartridge Locked" or LCK message disappears. The analyzer is ready for the next test immediately.



Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application. Do ensure that the instrument remains on a flat vibration-free surface for testing.

Procedure for Troponin I/cTnI CK-MB and BNP Cartridge Testing

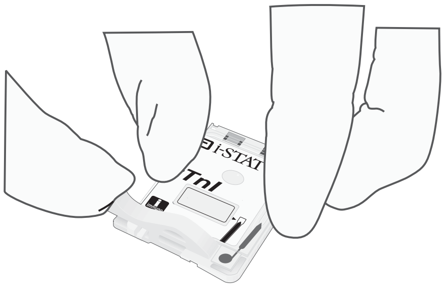
Note: The i-STAT cTnI, CK-MB and BNP cartridges can only be used with the i-STAT1Analyzer bearing the i immuno symbol.

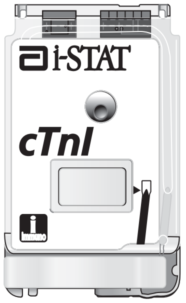
This symbol is located on the grey casing next to the lower right corner of the analyzer display screen. Before testing cTnI, CK-MB or BNP cartridges on the i-STAT 1 Analyzer, the analyzer must be customized through the Central Data Station (CDS) or through the analyzer's Customization menu for the following options:

1. Cartridge Information First Required AND Cartridge Lot Number Required, or
2. Cartridge Barcode Required.

Cartridge Test Procedure (Information First Customization)

1. Press the On/Off key to turn analyzer on.
2. Press 2 for i-STAT Cartridge from the Test Menu.
3. Scan or Enter Operator ID. Repeat if prompted.
4. Scan or Enter Patient ID. Repeat if prompted.
5. Scan Cartridge Lot number from the cartridge portion pack.
6. Remove cartridge from portion pack. Handle the cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
7. Following thorough mixing of the sample, discard 1 drop from the delivery device to clear unseen bubbles. Hang drop(s) slightly larger than the round "target well". Touch the drop to the well allowing cartridge to draw sample in. **Do NOT** load cartridge with a needle. Confirm sample volume lines up with top of "RED FILL LINE" diagram.
8. Close the cTnI CK-MB, or BNP cartridge:
    a. First anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet.
    b. Use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. Note: When sliding the closure clip, the index finger of that same hand *should not be placed directly across from the thumb*, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not at all.



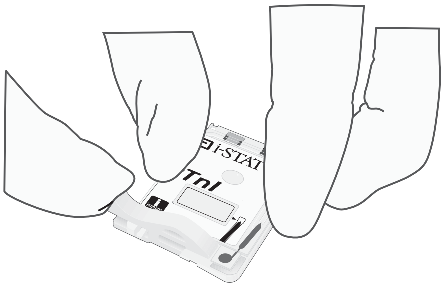


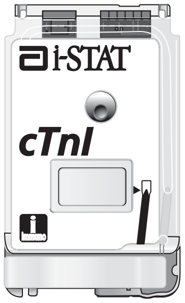
9. Insert cartridge into cartridge port. Grasp the cartridge "slide cover" between your first finger and thumb, using the thumb recess. Hold the analyzer in place with one hand. With the other **gently** guide the cartridge into the analyzer, releasing the cartridge **only after it is fully inserted.**

    The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
10. Select tests to be reported, if prompted.
11. Enter sample type on chart page, if applicable.
12. The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer's display.
13. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

Cartridge Test Procedure (Non-Information First Customization)

1. Remove cartridge from portion pack. Do not immediately dispose of the portion pack, as the cartridge lot number listed on it will be scanned into the analyzer during the testing procedure. Handle the cartridge from its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
2. Following thorough mixing of the sample, discard 1 drop from the delivery device to clear unseen bubbles. Hang drop(s) slightly larger than the round "target well". Touch the drop to the well allowing cartridge to draw sample in. **Do NOT** load cartridge with a needle. Confirm sample volume lines up with top of "RED FILL LINE" diagram.
3. Close the cTnI, CK-MB or BNP cartridge:
    a. first anchor the cartridge in place by using the thumb and index finger of one hand to grasp the cartridge from its side edges away from the sample inlet.
    b. use the thumb of the other hand to slide the plastic closure clip to the right until it locks into place over the sample well. Note: When sliding the closure clip, the index finger of that same *hand should not be placed directly across from the thumb*, as this could result in the sample being pushed onto the user's glove. This index finger should be placed just above the position of the sliding clip during closure or not used at all.

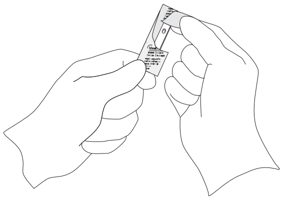




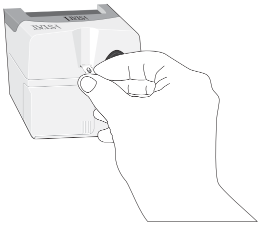
4. Insert the cartridge into the cartridge port. Grasp the cartridge "slide cover" between your first finger and thumb, using the thumb recess. Hold the analyzer in place with one hand. With the other **gently** guide the cartridge into the analyzer, releasing the cartridge **only after it is fully inserted.**
5. Scan the Cartridge Lot number from the cartridge portion pack.
6. Scan or Enter Operator ID. Repeat if prompted.
7. Scan or Enter Patient ID. Repeat if prompted.

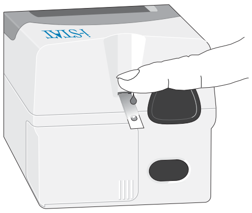
    The analyzer must remain on a level surface with the display facing up during testing. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.
8. Select tests to be reported, if prompted.
9. Enter sample type on chart page if applicable.
10. The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer's display.
11. Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.

PCx Glucose Test Strip Procedure



1. Press the ⏻ (On/Off) key to turn the analyzer on.
2. Press 3 for PCx Glucose Strip.
3. Press 1 for Patient.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter patient ID. Repeat if prompted.
6. Scan or enter test strip lot number.
7. Press 1 for Arterial/Capillary or 2 for venous sample if prompted.
8. Open foil packet, remove test strip and insert into analyzer test strip port with black contact bars facing up and forward.
9. Apply drop of blood to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)
10. Enter chart page information if applicable.
11. View results on analyzer’s display.
12. Enter Comment Code if applicable.
13. Remove and discard test strip.
    a. Do not handle test strip with wet or dirty hands.
    b. Do not scan the barcode of another test strip.
    c. Do not use test strips that are wet, scratched or damaged in any way.
    d. Do not re-use test strips.





Alternative Procedure

Should the i-STAT System become inoperable for any reason, specimens should be collected and submitted to the laboratory in accordance with the Laboratory Procedure Manual.

RESULTS

Calculations

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units. Electrolyte, chemistry and hematocrit results are also depicted as bar graphs with reference ranges marked under the graphs.

Suppressed Results

There are three conditions under which the i-STAT System will not display results:

1. Results outside the System's reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. (See the table of Reportable Ranges.) The < > flag indicates that the results for this test were dependant on the result of a test flagged as either > or <.

   Action:
   Send specimen(s) to the laboratory for analysis, if necessary.
2. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with *******.

   Action:
   Analyze the specimen again using a fresh sample and another cartridge. If the specimen integrity is not in question, the results that are not suppressed should be reported in the usual manner. If the result is suppressed again, send specimen(s) to the laboratory for analysis in accordance with the Laboratory Procedure Manual.
3. A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

   Action:
   Take the action displayed with the message that identifies the problem. Refer to the i-STAT or i-STAT 1 System Manual's Troubleshooting section or the "Analyzer Coded Messages" Technical Bulletin if necessary.

Printing and Transmitting Results

Printing Results from the i-STAT Portable Clinical Analyzer to the HP Portable Printer

1. Place the analyzer in the cradle of an IR Link or align the IR windows of the analyzer and printer. Turn the printer on (printer light red) or press the paper advance switch to reactivate.
2. To print the displayed test record, press the PRT key on the analyzer.
3. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT Key.
4. Do not move the analyzer while "Printing" is displayed.

   Optional: Write the patient's name on the "Pt Name" line and the physician's name on the "Physician" line.

   Note: Results printed on thermal paper will fade with time and are therefore not acceptable as a permanent chartable record.

Printing Results from the i-STAT Portable Clinical Analyzer to the Martel Portable Printer

1. Place the analyzer in the cradle of an IR Link or align the IR windows of the analyzer and printer. Turn the printer on by pressing the **Mode** button. The green status indicator will light.
2. To print the displayed test record, press the PRT key on the analyzer.
3. To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing the Key(s) corresponding to the numbers beside the record(s). Press the numbered key again to deselect a record. Then press the PRT Key
4. **Optional:** Write the patient's name on the "Pt Name" line and the physician's name on the "Physician" line.

   Note: Results printed on thermal paper will fade with time and are therefore not acceptable as a permanent chartable record.

Printing Results from the i-STAT 1 Analyzer to the Martel Portable Printer (Note: The HP printer and the Martel printers used with Portable Clinical Analyzer cannot be used with the i-STAT 1 Analyzer.)

Without Downloader or Downloader/Recharger

1. Turn printer on if green power light is not on.
2. Align IR windows of analyzer and printer.
3. Display results.
4. Press the Print key.
5. Do not move analyzer or printer until printing is complete.
6. If printer is not powered from a wall outlet, turn printer off.

With Downloader or Downloader/Recharger

1. Place analyzer in Downloader or Downloader/Rechrager that is wired to the printer.
2. Display results.
3. Press the Print key.
4. Do not move analyzer or printer until printing is complete.

Printing more than one result

1. Turn the analyzer on.
2. Press the Menu key.
3. Press 2 for Data Review.
4. Press 7 for List.
5. Scroll through the test records using the ← and → keys.
6. Press the numbered key for the test record(s). (Press the numbered key again to deselect a record.)
7. Align analyzer and printer IR window or place in Downloader or Downloader/Recharger attached to printer. Press the Print key.

Transmitting Results from the i-STAT Portable Clinical Analyzer to the Central Data Station

1. Place the analyzer in the cradle of an IR Link. The IR status light must be green.
2. With a test record on the display screen, press the * key.
3. Do not move the analyzer while “Transmitting” is displayed. During transmission the IR Link’s light will blink alternately red and green. If transmission is successful, the IR Link will emit a single high-pitched beep and the light will return to green. An unsuccessful transmission is indicated by three low tone beeps. In this case repeat the transmission process. If unsuccessful the second time, notify the i-STAT System Coordinator.

Transmitting Results from the i-STAT 1 Analyzer to the Data Manager

1. Place analyzer in a Downloader or Downloader/Recharger.
2. Do not move analyzer while the message “Communication in Progress” is displayed.

Reference Ranges[1,2], Reportable Ranges, and Test Unit Conversions

Reference range means the range of test values expected from 95% of fasting individuals presumed to be healthy. Reportable range means the range of test values throughout which the measurement system's results have been shown to be valid. The following table contains the Reference Ranges (for adults) and Reportable Ranges applicable to the i-STAT System.

Cartridges

ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE	UNIT CONVERSION
		(arterial)	(venous)		
Sodium	mmol/L (mEq/L)	138 – 146	138 - 146	100 – 180	mmol/L x 1 = mEq/L Example: 140 mmol/L = 140 mEq/L
Potassium	mmol/L (mEq/L)	3.5 – 4.9	3.5 - 4.9	2.0 – 9.0	mmol/L x 1 = mEq/L
Chloride	mmol/L (mEq/L)	98 – 109	98 – 109	65 – 140	mmol/L x 1 = mEq/L
BUN	mg/dL	8 – 26	8 – 26	3 – 140	mg/dL BUN x 0.357 = mmol urea/L Example: 20 mg/dL BUN = 7.1 mmol urea/L
UREA	mmol/L	2.9 – 9.4	2.9 – 9.4	1 – 50	
Glucose	mg/dL	70 – 105	70 – 105	20 – 700	mg/dL x 0.0556 = mmol/L Example:
	g/L	0.70 – 1.05	0.70 – 1.05	0.20 – 7.00	100 mg/dL = 5.55 mmol/L
	mmol/L	3.9 – 5.8	3.9 – 5.8	1.1 – 38.9	g/L x 5.556 = mmol/L
Creatinine	mg/dL	0.6 - 1.3	0.6 - 1.3	0.2 - 20.0	mg/dL x 88.4 = mmol/L
	mmol/L	53 - 115	53 - 115	18 - 1768	
Ionized Calcium	mmol/L	1.12 – 1.32	1.12 – 1.32	0.25 – 2.50	mmol/L x 4 = mg/dL
	mg/dL	4.5 – 5.3	4.5 – 5.3	1.0 – 10.0	Example: 1.13 mmol/L x 4 = 4.52 mg/dL
pH		7.35 – 7.45	7.31 – 7.41	6.50 – 8.20	N/A
PCO_2	mmHg	35 – 45	41 – 51	5 – 130	mmHg x 0.133 = kPa Example:
	kPa	4.67 – 6.00	5.47 – 6.80	0.67 – 17.33	35 mmHg x 0.133 = 4.66 kPa
pO_2	mmHg	80 – 105		5 – 800	mmHg x 0.133 = kPa
	kPa	10.7 – 14.0		0.7 – 106.6	Example: 83 mmHg x 0.133 = 11.04 kPa
TCO_2 (on the CHEM8+ cartridge only	mmol/L (mEq/L)	23-27	24-29	5-50	mmol/L x 1 = mEq/L

ANALYTE	UNIT	REFERENCE RANGE		REPORTABLE RANGE	UNIT CONVERSION
		(arterial)	(venous)		
Hematocrit	%PCV Fraction	38 – 51 0.38 – 0.51	38 – 51 0.38 – 0.51	10 – 75 0.10 – 0.75	% PCV x 0.01 = Volume fraction Example: 40% PCV = 0.40 PCV
Lactate	mmol/L mg/dL	0.36 –1.25 3.2 – 11.3	0.90-1.70 8.1–15.3	0.30 – 20.0 2.7 – 180.2	mmol/L x 9.01 = mg/dL
HCO_3*	mmol/L (mEq/L)	22 – 26	23 - 28	1.0 – 85.0	mmol/L x 1 = mEq/L
TCO_2* (on all cartridges but CHEM8+)	mmol/L (mEq/L)	23 – 27	24 - 29	5 – 50	mmol/L x 1= mEq/L
BE*	mmol/L (mEq/L)	(-2) – (+3)	(-2) – (+3)	(-30) – (+30)	
Anion Gap*	mmol/L (mEq/L)	10 – 20	10 – 20	(-10) – (+99)	
sO_2*	%	95 – 98		0 - 100	% x 0.01 = fraction saturated
Hb*	g/dL g/L mmol/L	12 – 17 120 – 170 7 – 11	12 – 17 120 – 170 7 – 11	3.4 – 25.5 34 – 255 2.1 – 15.8	g/dL x 10 = g/L
Celite ACT	seconds	74 – 125 (PREWRM) 84 – 139 (NONWRM)	74 – 125 (PREWRM) 84 – 139 (NONWRM)	50 - 1000	
Kaolin ACT	seconds	74 – 137 (PREWRM) 82 – 152 (NONWRM)	74 – 137 (PREWRM) 82 – 152 (NONWRM)	50 - 1000	
Prothrombin Time/PT	INR			0.9-8.0$^{\#}$	
Troponin I/cTnI	ng/mL (µg/L)		0.00 – 0.03** 0.00 – 0.08***	0.00 –50.00$^{\#\#}$	
Creatine Kinise MB/ CK-MB	ng/mL (µg/L)		0.0 – 3-5****	0.0-150.0	ng/mL x 1 = µg/L
B-Type Natrirebic Peptide/BNP	pg/mL (ng/L)		<15-50****	15-5000	pg/mL x 1 = ng/L

*Calculated values.
#Performance characteristics have not been established for INRs above 6.0.
**Represents the 0 – 97.5% range of results. Each facility should establish it's own reference range using the i-STAT cTnI assay.
$^{\#\#}$Performance characteristics have not been established for cTnI values above 35.00 ng/mL.
***Represents the 0-99% range of results. Each facility should establish it's own reference range using the i-STAT cTnI assay.
****Represents the 0-95% range of results. Each facility should establish it's own reference range using the i-STAT assay

Precision PCx Glucose Test Strip

UNIT	REFERENCE RANGE	REPORTABLE RANGE	UNIT OF CONVERSION
mg/dL	Fasting: 70 – 105 Two hours after meal: less than 140	20 – 600	mg/dL x 0.0556 = mmol/L
mmol/L	Fasting: 3.9 – 5.8 Two hours after meal: less than 7.8	1.1 – 33.3	

Precision PCx Plus Glucose Test Strip

UNIT	REFERENCE RANGE	REPORTABLE RANGE	UNIT OF CONVERSION
mg/dL	Fasting: 70 – 105 Two hours after meal: less than 140	20 – 500	mg/dL x 0.0556 = mmol/L
mmol/L	Fasting: 3.9 – 5.8 Two hours after meal: less than 7.8	1.1 – 27.8	

Critical Results[3]

Critical results are test results that fall outside high and low critical limits that define the boundaries of life-threatening values for a test. Critical results represent an emergency condition and must be reported immediately to the patient's attending physician or nurse.

ANALYTE (units)	ADULT		CHILDREN		NEONATES	
	low	**high**	**low**	**high**	**low**	**high**
Sodium (mmol/L)	120	158	121	156	121	156
Potassium (mmol/L)	2.8	6.2	2.8	6.4	2.8	6.5
Chloride (mmol/L)	75	126	77	121	77	121
TCO_2 (mmol/L)	11	40	11	39	–	–
Ionized Calcium (mmol/L)	0.78	1.58	0.74	1.57	–	–
pH	7.21	7.59	7.21	7.59	–	–
PCO_2 (mmHg)	19	67	21	66	–	–
PO_2 (mmHg)	43	–	45	124	37	92
BUN (mg/dL)	–	104	–	55	–	55
Glucose (mg/dL)	46	484	46	445	32	328
Creatinine	–	7.4	–	3.8	–	–
Lactate						
Hematocrit (%PCV)	18	61	20	62	33	71
Celite ACT						
Kaolin ACT						
PT/INR						
Troponin I/cTnI						
Creatine Kinase MB/ CK-MB						
B-Type Natriuretic Peptide/ BNP						

Interferences

An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured. For example, in the table below, β-hydroxybutyrate at sample concentration level of 16 mmol/L would decrease the measured sodium by 5 mmol/L.

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
Sodium	β-hydroxybutyrate	16 mmol/L (166 mg/dL)	Decrease (↓) Na by 5 mmol/L
	Lactate	20 mmol/L	Decrease (↓) Na by 5 mmol/L
	Bromide	37.5 mmol/L	Increase (↑) Na by 5 mmol/L
Chloride	β-hydroxybutyrate	16 mmol/L (166 mg/dL)	Increase (↑) Cl by 3 mmol/L
	Bromide	12.5 mmol/L (100 mg/dL)	Increase (↑) Cl by 30 mmol/L
	Lactate	11 mmol/L (100 mg/dL)	Increase (↑) Cl by 3.5 mmol/L
	Salicylate	4 mmol/L	Increase (↑) Cl by 5 mmol/L
	Thiocyanate	24 mmol/L (140 mg/dL)	May cause falsely elevated chloride results, or to be suppressed (***)
Ionized Calcium	Magnesium	1.0 mmol/L above normal	Increase (↑) iCa by 0.04 mmol/L
	β-hydroxybutyrate	20 mmol/L	Decrease (↓) iCa by 0.1 mmol/L
	Lactate	20 mmol/L	Decrease (↓) iCa by 0.05 mmol/L
	Salicylate	4.34 mmol/L	Decrease (↓) iCa by 0.1 mmol/L
Glucose	Bromide	37.5 mmol/L (300 mg/dL)	Decrease (↓) glucose by 30 mg/dL
(Cartridge)	pH	pH: per 0.1 pH units below 7.4 @ 37°C	Decrease (↓) glucose by 0.9 mg/dL (0.05 mmol/L)
		pH: per 0.1 pH units above 7.4 @ 37°C	Increase (↑) glucose by 0.8 mg/dL (0.04 mmol/L)
	Oxygen	PO_2 less than 20 mmHg @ 37°C	May decrease (↓) glucose
	Hydroxyurea	100 µmol/L	Increase (↑) glucose 8 mg/dL (0.44 mmol/L)
	Thiocyanate	24 mmol/L (140 mg/dL)	Decrease (↓) glucose by approx. 23%
Glucose	Hematocrit	<20%PCV	Increase (↑) glucose
(Precision PCx Test Strip)		>70%	Decrease (↓) glucose
	Acetominophen	>100 µg/mL	Decrease (↓) glucose
Glucose **(Precision PCx Plus Test Strip)**	See package insert for full details.		
BUN/Urea	Thiocyanate	24 mmol/L (140 mg/dL)	Decrease (↓) urea by approx. 21%
Lactate (continued age)	Bromide	25 mmol/L (200 mg/dL)	Decrease (↓) lactate by 40%
	Cysteine	6.4 mmol/L (101 mg/dL)	Decrease (↓) lactate by 11%
	Hydroxyurea	100 µmol/L	Increase (↑) lactate1.44 mg/dL (0.16 mmol/L)

ANALYTE	INTERFERENT	INTERFERENT CONCENTRATION	EFFECT ON ANALYTE RESULT
	Glycolic Acid	10 mmol/L	Increase (↑) lactate by approx. 1.96 mmol/L from an initial Lactate concentration of 1.45 mmol/L
Creatinine	Acetaminophen	For every 1 mmol/L acetaminophen	Increase (↑) creatinine by 0.25 mg/dL
	Ascorbate	0.227 mmol/L	Increase (↑) creatinine by 0.7 mg/dL
	Bromide	12.5 mmol/L (100 mg/dL)	Increase (↑) creatinine by 0.8 mg/dL (71 Mmol/L) from an initial Creatinine concentration of 1.0 mg/dL (88 Mmol/L)
<2 mg/dL	$P\text{CO}_2$	Above 40 mmHg	Increase (↑) creatinine by 6.9% per 10 mmHg $P\text{CO}_2$
		Below 40 mmHg	Decrease (↓) creatinine by 6.9% per 10 mmHg $P\text{CO}_2$
>2 mg/dL	$P\text{CO}_2$	Above 40 mmHg	Decrease (↓) creatinine by 3.7% per 10 mmHg $P\text{CO}_2$
		Below 40 mmHg	Increase (↑) creatinine by 3.7% per 10 mmHg $P\text{CO}_2$
	Hydroxyurea	100 µmol/L	Increase (↑) 1.85 mg/dL (164 µmol/L)
	Creatine	5 mg/dL creatine	Increase (↑) creatinine by 0.20 mg/dL
	N-acetylcysteine	16.6 mmol/L	Increase (↑) creatinine by 0.4 mg/dL
Hematocrit	White Blood Count (WBC)	Greater than 50,000 WBC/µL	May Increase (↑) hematocrit
	Total Protein	For measured Hct<40% For each g/dL below 6.5 For each g/dL above 8.0	 Decrease (↓) Hct by 1% PCV Increase (↑) Hct by 1% PCV
		For measured Hct≥40% For each g/dL below 6.5 For each g/dL above 8.0	 Decrease (↓) Hct by 0.75% PCV Increase (↑) Hct by 0.75% PCV
	Lipids	Abnormally high	Increase (↑) Hct
Celite ACT	Aprotinin		Falsely extends Celite ACT times
PCO_2	Propofol (Diprovan®) Thiopental Sodium		For patients administered propofol or thiopental sodium, i-STAT recommends the use of G3+, CG4+, CG8+, EG6+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.

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QUALITY CONTROL

Daily Procedures

Analyzer Verification

Verify the performance of each handheld analyzer or Blood Analysis Module in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit, ACT, PT/INR, cTnI, CK-MB, and BNP.

Action:

If PASS is displayed on the analyzer screen (after using the external Electronic Simulator):

- ☐ Remove the Electronic Simulator after the LCK or Simulator Locked message disappears from the display screen.
- ☐ Transmit the result to the Central Data Station.
- ☐ Use the analyzer as required.

Note: If the internal Electronic Simulator is used, the “PASS” message will not be displayed on the analyzer screen. The “PASS” record will appear in the analyzer’s stored results for transmission to the Central Data Station.

Remedial Action:

If FAIL is displayed on the analyzer screen:

- ☐ Repeat the procedure with the same Electronic Simulator or rerun the cartridge if the internal Electronic Simulator is being used. If PASS is displayed use the analyzer as required.
- ☐ If FAIL is displayed repeat the procedure with a different external Electronic Simulator.

If PASS is displayed with the second Electronic Simulator:

- ☐ Use the analyzer as required.
- ☐ Deliver the questionable Electronic Simulator to the i-STAT System Coordinator.

If FAIL is displayed with the second Electronic Simulator:

- ☐ DO NOT analyze patient samples with the analyzer.
- ☐ Transmit the results to the Central Data Station.
- ☐ Deliver the faulty analyzer to the i-STAT System Coordinator.
- ☐ Record the failure in the i-STAT QC Log along with the action taken.

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

- ☐ Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Deliver any expired cartridges to the i-STAT System Coordinator.
- ☐ Verify that the refrigerator did not exceed the limits of 2 to 8°C (35 to 46°F).
- ☐ Document in the i-STAT QC Log.

Action:

If the temperature of the cartridge storage refrigerator is within the range of 2 to 8°C (35 to 46°F) use cartridges as required.

Remedial Action:

If the temperature is outside the range of 2 to 8°C (35 to 46°F), quarantine the cartridges in the storage refrigerator. Notify the i-STAT System Coordinator immediately. DO NOT USE the cartridges from this refrigerator. Record the QC failure in the i-STAT QC Log along with the action taken.

Room Temperature Cartridges

- ☐ Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than two weeks. Deliver any expired cartridges to the i-STAT System Coordinator.
- ☐ Verify that room temperature has not exceeded 30°C.
- ☐ Document in the i-STAT QC log.

Action:

If the measured temperature of the room has been continuously below 30°C (86°F) use cartridges as required.

Remedial Action:

If the measured room temperature has exceeded 30°C (86°F) for any period of time:

- ☐ Quarantine the cartridges.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ DO NOT USE the cartridges.
- ☐ Record the out-of-control event in the i-STAT QC Log and the action taken.

Periodic Procedures for Glucose Test Strips

- ☐ Two levels, usually the Low and High Controls, are tested:
- ☐ When a new lot of test strips is opened.
- ☐ When diabetes medication plan is adjusted.
- ☐ When the strips have been exposed to temperatures outside the storage conditions (4-30°C, 39-86 °F).

1. Press the ⏼ (On/Off) key to turn the analyzer on.
2. Press 3 for PCx Glucose Strip.
3. Press 2 for Control.
4. Scan or enter operator ID. Repeat if prompted.
5. Scan or enter Low Level Control lot number.
6. Scan or enter test strip lot number.
7. Open foil packet, remove test strip and insert into analyzer test strip port with black contact bars facing up and forward.
8. Apply Control solution to target area of test strip. Cover the entire area. Do not touch the test strip after sample is applied. (If test fails to start after second drop applied or if more than 30 seconds have passed, discard test strip and repeat the test.)
9. Enter chart page information if applicable.
10. View results on analyzer's display.
11. Enter Comment Code if applicable.
12. Remove and discard test strip.
    a. Do not handle test strip with wet or dirty hands.
    b. Do not scan the barcode of another test strip.
    c. Do not use test strips that are wet, scratched or damaged in any way.
    d. Do not re-use test strips.
13. Press 1 for Test Options and 1 for Next Level if testing another level of control.

Action:

If the results are PASS, use the test strips as needed.

Remedial Action:

If the result is outside the acceptable range:

- ☐ Check that the correct lot numbers for control and test strip were scanned.
- ☐ Check storage conditions and that bottle has not been opened for more than 90 days.
- ☐ Use a new test strip. If results are in range, continue to use the test strips. If not, do not use the strips from this lot and notify the i-STAT System Coordinator.

Monthly Procedures

Print Electronic Simulator Results

Print a copy of the Electronic Simulator results from the Central Data Station. Include the report in the i-STAT QC Log.

- ☐ CDS version lower than 5: Click on System and Electronic Simulator.
- ☐ CDS version 5 and above: Click on the Simulator Viewer.

Print Control Fluid Analysis Results

Print results for any control fluids analyzed from the Central Data Station. Include the report in the i-STAT QC Log.

- ☐ CDS version lower than 5: Use the Trend function.
- ☐ CDS version 5 and above: Click on the Control Results Viewer.

Periodic Procedures for Cartridges

For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing.

Check Temperature Monitor

i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit.

Action:

- ☐ Fill out the record of receipt and forward materials to refrigerator.
- ☐ If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used.

Remedial Action:

If the C or D windows are blue, or the 3 or 4 windows are red:

- ☐ Quarantine the suspect cartons.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ DO NOT USE cartridges from the suspect cartons.
- ☐ Record the out-of-control event in the i-STAT QC Log.

Integrity Testing

From each lot of blood gas/chemistry cartridges received, use a representational number of cartridges to analyze i-STAT Level 1 and 3 Controls. For CHEM8+ cartridges, analyze i-STAT CHEM8+ Control Levels 1 and 3. If hematocrit is included, also analyze RNA Medical Hematocrit Control Level 1 and 3 or Meter Trax Low and High Controls. For ACT cartridges, analyze i-STAT Level 1 and Level 2 ACT Controls. For PT/INR cartridges, analyze i-STAT Level 1 and Level 2 PT Controls. For cTnI cartridges, analyze i-STAT Level 1 and Level 3 Cardiac Marker Controls. For CK-MB cartridges, analyze CLINIQA Cardiac Marker Level 1 and 3 controls. For BNP cartridges, analyze i-STAT, BNP Control Levels 1 and 3. Use any verified analyzer for control testing. Transmit the results to the Central Data Station. Use the expected values published in the package inserts to verify the integrity of the cartridges.

Procedure for testing cartridges with i-STAT Level 1 and Level 3 Controls:

1. Prior to testing cartridges that measure ***P***O2, ampules should stand at room temperature a minimum of 4 hours before use. When testing other cartridges (G, Crea, E3+, EC4+, 6+ or EC8+), ampules may be used once the fluid has reached room temperature, approximately 30 minutes for individual ampules. For best results, ampules, cartridges, and analyzers should be at the same temperature. When using cartridges that contain sensors for measuring ionized calcium, pH, ***P***CO_2, or ***P***O_2 (G3+, EG6+, EG7+, CG4+, CG8+, or EC8+), a separate ampule must be used for each cartridge being tested; if these sensors are not present (i.e., the 6+ cartridge), the contents of one ampule may be used to fill
   more than one cartridge as long as the cartridges are filled and inserted into an analyzer within 10 minutes of opening the ampule.
2. Immediately before use, shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule. Protect fingers with gauze, tissue, or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
3. Immediately transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge. Immediately seal the cartridge and insert it into an analyzer. It is important not to expose the solution to room air since this will alter the results.
   - ☐ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tube rests at the bottom of the ampule, uncover the other end to allow filling by capillary action.
   - ☐ When using a syringe (1cc or 3cc syringes with 16 to 20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.
   - ☐ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of the cartridges that contain sensors for ionized calcium, pH, ***P***CO_2, or ***P***O_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
4. Compare results to the package insert values. Check that the lot number on the control ampule matches the lot number on the package insert and that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed. Transmit the results to the Central Data Station.

Procedure for testing CHEM8+ cartridges with i-STAT CHEM8+ controls.

1. Equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.
2. Immediately before use, shake the ampule vigorously for 5-10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
3. Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
4. Immeditely transfer the solution from the ampule into a plain capillary tube or plain syringe, and then immediately transfer the solution into a cartridge.
5. Immediately seal the cartridge and insert it into an analyzer – it is important not to expose the solution to room air since this will alter the results.
   - ☐ When using a capillary tube, fill from the bottom of the ampule. Avoid drawing solution from the surface by covering the far end of the tube as it is inserted into the ampule. Once the open end of the tubes at the bottom of the ampule, uncover the other end to allow filling by capillary action.
   - ☐ When using a syringe (1 cc or 3 cc syringes with 16-20 gauge needles are recommended), slowly draw approximately 1 mL of solution from the bottom of the ampule. If air is trapped between the leading edge of the solution and the plunger, do NOT invert the syringe to expel it; this will not affect solution near the tip of the syringe. If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe and use a fresh ampule and syringe. Expel one or two drops from the syringe before filling the cartridge.

- ☐ Do not use solution left in the syringe, ampule, or capillary tube for additional testing of CHEM8+ cartridges.

6. Compare results to the package insert values. Check that the lot number on the control ampule matches the lot number on the package insert that the software version listed on the insert matches the software installed in the analyzer. If all results are within expected ranges, use the cartridges as needed. Transmit the results to the Central Data Station.

Procedure for testing cartridges with Hematronix Meter Trax Controls for Hematocrit

1. Warm Meter Trax to room temperature, 18 - 30°C (64 -86°F).
2. Roll the vials upright in the palms several times, then invert the vials and repeat rolling in the palms several times. Continue inverting and mixing the vials for 2-3 minutes. Verify the uniform mixing of the vials by checking for clumping on the sides and bottom of the vials. If clumping is present, continue to roll the vials until all clumps are gone. If clumping remains after 5 minutes, discard the vial.
3. Fill and seal a cartridge and insert immediately into the analyzer. Note: The Control option from the Quality Tests menu must be used on the i-STAT 1 Analyzer for Meter Trax controls.
4. After completion of testing, wipe the rim of the cap of the vial with a lint-free wipe, recap and return to the refrigerator.
5. Compare results to the package insert values. If results are within the expected ranges, use the cartridges as needed. Transmit results to the Central Data Station.

Procedure for testing cartridges with RNA Medical Hematocrit controls

1. If stored refrigerated, the control material should be equilibrated to room temperature for at least four (4) hours prior to use. If stored at room temperature, no equilibration of the control material is necessary.
2. Gently invert the ampule to mix the solution. Tap the ampule to restore the liquid to the bottom of the ampule.
3. Open the ampule by snapping off the tip at the neck. Use gauze, tissue, gloves, or an appropriate ampule opener to protect fingers from cuts.
4. Fill and seal a cartridge and insert immediately into the analyzer. Note: the Control option from the Quality Tests menu must be used on the i-STAT 1 Analyzer for RNA Medical Hematocrit Control.
5. Compare the i-STAT System Hematocrit result to the package insert value. Note: the only value assigned to this fluid is for hematocrit. All other cartridge analyte results obtained with this control material should be ignored.
6. If available, transmit results to the Central Data Station.

Remedial Action:

If any results are outside the published expected ranges:

- ☐ DO NOT USE cartridges from the suspect lot.
- ☐ Quarantine the suspect lot.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing cartridges with i-STAT Level 1 and Level 2 ACT or PT/INR Controls

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
3. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minute, then inverting slowly for 30 seconds.
4. Use a plastic pipette, syringe, or capillary tube without anticoagulant to transfer the solution to an ACT cartridge.
5. Immediately seal the cartridge and insert it into an analyzer. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
6. Compare results to the package insert values. If results are within the expected ranges, use the cartridges as needed. Transmit results to the Central Data Station.

Remedial Action:
If any results are outside the published expected ranges:

- ☐ DO NOT USE cartridges from the suspect lot.
- ☐ Quarantine the suspect lot.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing cTnI cartridges with i-STAT Level 1, 2, or 3 Cardiac Marker Controls:

1. Remove vial from freezer and thaw at room temperature (18-30ºC) for 15 minutes.
2. Thoroughly mix by gently swirling the bottle. Avoid foaming of the sample.
3. Dispense a drop of sample directly from the vial into the i-STAT cTnI cartridge and seal the cartridge. If short-term storage (<4 hrs) is desired, tightly recap the bottle immediately, and store at 2-8ºC.
4. Insert cartridge into an i-STAT 1 Analyzer.

Target Values and Ranges: See value assignment sheet accompanying the control or calibration verification material. The value assignment sheet displays target values and ranges expected when materials and equipment are performing properly. Should results fall outside the range, refer to the System Manual.

Always ensure that the lot number and software revision on the value assignment sheet matches the lot number of the vial in use and the software revision in the analyzer.

Target values are specific to the i-STAT System. Results may differ if used with other methods (i.e., other IVD instrumentation).

Always remember to analyze the control material in the Control pathway and the calibration verification material in the Cal Ver pathway under the Quality Tests option of the i-STAT 1 Analyzer Administration Menu.

Remedial Action:
If any results are outside the published expected ranges:

- ☐ DO NOT USE cartridges from the suspect lot.
- ☐ Quarantine the suspect lot.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedures for for testing CK-MB cartridges with CLINIQA Cardiac Marker controls for i-STAT

1. CLINIQA Liquid QC Cardiac Marker Control is a ready-to-use liquid control requiring no reconstitution or frozen storage. It is stable until the expiration date on the vial label when stored unopened at 2-8°C. Once opened, CLINIQA Liquid QC Cardiac Marker Control is stable for 30 days when stored tightly capped at 2-8°C.
2. Immediately before use, gently mix the contents of the control vial to ensure homogeneity. Avoid foaming of the sample.
3. Open the vial and transfer a drop of the solution into the i-STAT CK-MB cartridge using a plain capillary tube, plain syringe, or plastic transfer pipette. Tightly recap the control vial and store it at 2-8°C.
4. Seal the cartridge and immediately insert it into the i-STAT 1 Analyzer.
5. Compare the i-STAT CK-MB result to the package insert value. Always ensure that the lot number and software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the analyzer.
6. If available, transmit results to the Central Data Station.

Remedial Action

If any results are outside the published expected ranges:

- ☐ DO NOT USE cartridges from the suspect lot.
- ☐ Quarantine the suspect lot.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ Record the QC failure in the i-STAT QC Action Log along with the action taken.

Procedure for testing BNP cartridges with i-STAT BNP Level 1, 2, or 3 Controls

1. Remove vial from freezer and thaw at room temperature (18-30°) for 15 minutes.
2. Gently invert the vial 10 times, then swirl the vial 10 times. Inspect the sides of the vial to ensure that no particulate matter is clinging to the sides of the vial. If solids are observed in the control fluid or on the vial wall, repeat the mixing procedure. If further mixing does not homogenize the sample, discard the vial and thaw a fresh vial.
3. Open the vial and transfer a drop of solution directly into the BNP cartridge and seal the cartridge. If short term storage (<4 hours) is desired, tightly recap the bottle immediately, and store at 2-8°C.
4. Seal the cartridge and insert into the i-STAT 1 Analyzer.
5. Compare the i-STAT BNP result to the package insert value. Always ensure that the lot number and the software revision on the Value Assignment Sheet matches the lot number of the vial in use and the software revision in the analyzer.
6. If available, transmit results to the Central Data Station.

Remedial Action

If any results are outside the published expected ranges:

- ☐ DO NOT USE cartridges from the suspect lot.
- ☐ Quarantine the suspect lot.
- ☐ Notify the i-STAT System Coordinator immediately.
- ☐ Record the QC failure in the i-STAT QC Action Log along with the action taken.

CALIBRATION

For cartridges, calibration is automatically performed as part of the test cycle on each cartridge type, except coagulation and immunoassay cartridges. Operator intervention is not necessary.

For glucose test strips, lot-specific calibration information is encoded in the test strip barcode label.

CLINICAL SIGNIFICANCE

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Sodium	Dehydration Diabetes insipidus Salt poisoning Skin losses Hyperaldosteronism CNS disorders	Dilutional hyponatremia (cirrhosis) Depletional hyponatremia Syndrome of inappropriate ADH
Potassium	Renal glomerular disease Adrenocortical insufficiency Diabetic Ketoacidosis (DKA) Sepsis *In vitro* hemolysis	Renal tubular disease Hyperaldosteronism Treatment of DKA Hyperinsulinism Metabolic alkalosis Diuretic therapy
Chloride	Prolonged diarrhea Renal tubular disease Hyperparathyroidism Dehydration	Prolonged vomiting Burns Salt-losing renal disease Overhydration Thiazide therapy
Ionized Calcium	Dehydration Hyperparathyroidism Malignancies Immobilization Thiazide diuretics Vitamin D intoxication	Hypoparathyroidism Early neonatal hypocalcemia Chronic renal disease Pancreatitis Massive blood transfusions Severe malnutrition
BUN	Impaired renal function Prerenal azotemia (e.g. shock) Postrenal azotemia GI bleeding High protein diet	Pregnancy Severe liver insufficiency Overhydration Malnutrition
Glucose	Diabetes mellitus Pancreatitis Endocrine disorders (e.g. Cushing’s syndrome) Drugs (e.g. steroids, thyrotoxicosis) Chronic renal failure Stress IV glucose infusion	Insulinoma Adrenocortical insufficiency Hypopituitarism/Massive liver disease Ethanol ingestion/Reactive hypoglycemia Glycogen storage disease

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
Creatinine	Impaired renal function	
Lactate	Hypoxia (shock, hypovolumia, left ventricular failure); diabetes mellitus, neoplasia, liver disease; drug or toxins (ethanol, methanol, salicylates); glycolic acid as a product of ethylene glycol metabolism	
pH	Respiratory alkalosis Metabolic alkalosis	Respiratory acidosis Metabolic acidosis
PCO$_2$	Acute Respiratory Acidosis: • *Depression of respiratory center* • *Suppressed neuromuscular system* • *Pulmonary disorders* • *Inadequate mechanical ventilation* Chronic respiratory acidosis • *Decreased alveolar ventilation* • *Hypoventilation* Compensation in metabolic alkalosis	Respiratory alkalosis: • *Increased stimulation of respirator center* • *Hypermetabolic states* • *Mechanical hyperventilation* Compensation in metabolic acidosis
PO$_2$	Breathing oxygen-enriched air	Carbon-monoxide exposure Pulmonary disorders Myocardial infarction Congestive heart failure
HCO$_3$	Primary metabolic alkalosis Primary respiratory acidosis	Primary metabolic acidosis Primary respiratory alkalosis
Hematocrit	Dehydration Burns Impaired ventilation Renal disorders	Hemolytic anemias Iron deficiency Marrow depression Blood loss
ACT Celite	Administration of heparin for medical or surgical procedures. Administration of aprotinin.	

Analyte	Some Causes of Increased Values	Some Causes of Decreased Values
PT/INR	Administration of oral anticoagulant therapy.	
ACT Kaolin	Administration of heparin for medical or surgical procedures.	
cTnI	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Rhythm disturbance (SVT, AF) Chemotherapy (ex. Adriamycin) Myocarditis/pericarditis Infiltrative diseases (ex. Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Congestive heart failure Heart transplantation Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions	Rare antibodies to troponin or its circulating complexes
CK-MB	Myocardial Infarction Coronary vasospasm Cardiac contusion/trauma Myocarditis/pericarditis Infiltrative diseases (ex. Amyloidosis, sarcoidosis, hemochromatosis, connective tissue disease) Cardiac procedures (PTCA, DC cardioversion) Intracranial hemorrhage/stroke Pulmonary embolism Pulmonary hypertension Chronic renal insufficiency Sepsis Strenuous exercise Certain drug ingestions (cocaine) Skeletal muscle disease	Lean muscle mass
BNP	Congestive heart failure Chronic obstructive pulmonary disease (COPD) Asthma Pulmonary hypertension Cor pulmonale Pulmonary embolism Acute coronary syndrome Chronic renal failure Age Female sex	Obesity (BMI>30 Kg/m^2) Flash pulmonary edema (elevation may be delayed)

PRINCIPLES OF MEASUREMENT

Sodium, Potassium, Chloride, Ionized Calcium, pH, and PCO_2

are measured by ion-selective electrode potentiometry. Concentrations are calculated from the measured potential through the Nernst equation.

Urea

is first hydrolyzed to ammonium ions in a reaction catalyzed by the enzyme urease. The ammonium ions are measured by an ion-selective electrode and the concentration is calculated from the measured potential through the Nernst equation.

Glucose

is measured amperometrically. Oxidation of glucose, catalyzed by the enzyme glucose oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at an electrode to produce an electric current which is proportional to the glucose concentration.

Creatinine

is hydrolyzed to creatine in a reaction catalyzed by the enzyme creatinine amidohydrolase. Creatine is then hydrolyzed to sarcosine in a reaction catalyzed by the enzyme creatine amidinohydrolase. The oxidation of sarcosine, catalyzed by the enzyme sarcosine oxidase, produces hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the creatinine concentration.

Lactate

is measured amperometrically. The enzyme lactate oxidase, immobilized in the lactate biosensor, selectively converts lactate to pyruvate and hydrogen peroxide. The liberated hydrogen peroxide is oxidized at the platinum electrode to produce a current which is proportional to the sample concentration.

PO_2

is measured amperometrically. The oxygen sensor is similar to a conventional Clark electrode. Oxygen permeates through a gas permeable membrane from the blood sample into an internal electrolyte solution where it is reduced at the cathode. The oxygen reduction current is proportional to the dissolved oxygen concentration.

Hematocrit

is determined conductometrically. The measured conductivity, after correction for electrolyte concentration, is inversely related to the hematocrit.

ACT

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with a particulate clotting activator – either Celite® brand diatomaceous earth or kaolin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and the result is reported as a whole blood time (WBT).

Glucose Test Strip

is determined amperometrically. Each strip includes an electrode containing the enzyme glucose oxidase (Precision PCx) or glucose dehydrogenase (PCx Plus). When a drop of blood is applied to the target area of the test strip, the glucose oxidase or dehydrogenase catalyzes the oxidation of glucose in the drop to produce gluconic acid. During the reaction, electrons are transferred by an electrochemical mediator to the electrode surface. This generates a current that is measured by the system. The size of the current generated is proportional to the amount of glucose present in the blood drop.

PT/INR

is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has as amide linkage that mimics the thrombin–cleaved amide linkage in fibrinogen. The product of the thrombin–substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR and/or seconds.

Troponin I/cTnI

is determined amperometrically using a two-site ELISA method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of cTnI within the sample.

Creatine Kinase MB/CK-MB

is determined amperometrically using a two-site ELISA method. Antibodies specific for an epitope unique to the CK-MB subunit, that therefore do not bind CK-MM or CK-BB, are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to an epitope on the B subunit of creatine kinase. The specificity of the conjugate antibody to the B subunit allows this conjugate to recognize CK-MB and CK-BB, but not CK-MM. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The CK-MB within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately three minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of CK-MB within the sample.

B-Type Natriuretic Peptide/BNP

is determined amperometrically using a two-site ELISA method. Antibodies specific for BNP are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the BNP molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The BNP within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample is washed off the sensors, as well as excess enzyme conjugate. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product which is proportional to the concentration of BNP within the sample.

FOOTNOTES

1. Statland, B.E., Clinical Decision Levels for Lab Tests. Medical Economics Books, 1987.
2. Tietz, N.W., Tietz Textbook of Clinical Chemistry, third edition, Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders Company, Philadelphia, 1999. Table 50 – 20, Appendix.
3. Kost, Gerald J., Using critical limits to improve patient outcome. Medical Laboratory Observer. March 1993; 25(3): 22–27.

Prepared By:______________________________ Date: ______________________

Adopted: ______________________________ Date: ______________________

Reviewed:______________________________ Date: ______________________

Reviewed:______________________________ Date: ______________________

Reviewed:______________________________ Date: ______________________

Revised: ______________________________ Date: ______________________

i-STAT QC Log: Incoming QC

Cartridge Type:__________________ **Lot No.:**__________________ **Rec'd Date:** ______________ **Quant.**_____________ **Temp.Strip**_________

Control Name: ___________________ **Lot No.:** __________________ **Level:** _____________ **Exp. Date:** _______________ **CLEW:** _______________

Test									
Range									
Results									
Results									

Control Name: ___________________ **Lot No.:** __________________ **Level:** _____________ **Exp. Date:** _______________ **CLEW:** _______________

Test									
Range									
Results									
Results									

Control Name: ___________________ **Lot No.:** __________________ **Level:** _____________ **Exp. Date:** _______________ **CLEW:** _______________

Test									
Range									
Results									
Results									

Lot/Shipment accepted by: ____ **Date:** ___________________________

i-STAT QC Action Log

Date	Cartridge Type	Cartridge Lot No.	Date Rec'd	Quantity	Test(s) Out of Range	Corrective Action	Inspector

i-STAT QC Log: Expiration Date and Storage Conditions: Refrigerated

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Inspector

i-STAT QC Log: Expiration Date and Storage Conditions: Room Temperature

Date	Location	Cartridge Type	Lot #	Exp. Date	Quantity	Temp.	Action	Inspector

i-STAT Electronic Simulator Log for Analyzer Serial Number:________________________ Year:__________________________

Date	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator	Time	Pass Fail	Simulator ID	Operator

i-STAT Electronic Simulator Action Log

Date	Time	Analyzer	Failure Code or Letter	Simulator ID	Action	Pass Fail	Operator

i-STAT 1 Analyzer PCx and PCx Plus Glucose Test Strip QC Log

Date	Time	Control Level	Control Lot	Strip Lot	Pass Fail	If Fail Expected Range	Result	Action	Operator